Kakatiya University, Warangal

Syllabus for the Bachelor of Pharmacy (B. Pharm) Four Years Course

From the academic year 2017-2018 onwards

CHAPTER- I: REGULATIONS

1. Short Title and Commencement

These regulations shall be called as "The Revised Regulations for the B. Pharm. Degree Program (CBCS) of the Pharmacy Council of India, New Delhi". They shall come into effect from the Academic Year 2017-18. The regulations framed are subject to modifications from time to time by Pharmacy Council of India.

2. Minimum qualification for admission

First year B. Pharm:

Candidate shall have passed 10+2 examination conducted by the respective state/central government authorities recognized as equivalent to 10+2 examination by the Association of Indian Universities (AIU) with English as one of the subjects and Physics, Chemistry, Mathematics (P.C.M) and or Biology (P.C.B / P.C.M.B.) as optional subjects individually. Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.

2.2. B. Pharm lateral entry (to third semester):

A pass in D. Pharm. course from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.

3. Duration of the program

The course of study for B.Pharm shall extend over a period of eight semesters (four academic years) and six semesters (three academic years) for lateral entry students. The curricula and syllabi for the program shall be prescribed from time to time by Pharmacy Council of India, New Delhi.

4. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

5. Working days in each semester

Each semestershall consist of not less than 100 working days. The odd semesters shall be conducted from the month of June/July to November/December and the even semesters shall be conducted from December/January to May/June in every calendar year.

6. Attendance and progress

A candidate is required to put in at least 80% attendance in individual courses considering theory and practical separately. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

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7. Program/Course credit structure

As per the philosophy of Credit Based Semester System, certain quantum of academic work viz. theory classes, tutorial hours, practical classes, etc. are measured in terms of credits. On satisfactory completion of the courses, a candidate earns credits. The amount of credit associated with a course is dependent upon the number of hours of instruction per week in that course. Similarly, the credit associated with any of the other academic, co/extra-curricular activities is dependent upon the quantum of work expected to be put in for each of these activities per week.

Credit assignment

Theory and Laboratory courses

Courses are broadly classified as Theory and Practical. Theory courses consist of lecture (L) and /or tutorial (T) hours, and Practical (P) courses consist of hours spent in the laboratory. Credits (C) for a course is dependent on the number of hours of instruction per week in that course, and is obtained by using a multiplier of one (1) for lecture and tutorial hours, and a multiplier of half (1/2) for practical (laboratory) hours. Thus, for example, a theory course having three lectures and one tutorial per week throughout the semester carries a credit of 4. Similarly, a practical having four laboratory hours per week throughout semester carries a credit of 2.

Minimum credit requirements

The minimum credit points required for award of a B. Pharm. degree is 208. These credits are divided into Theory courses, Tutorials, Practical, Practice School and Projectover the duration of eight semesters. The credits are distributed semester-wise as shown in Table IX. Courses generally progress in sequences, building competencies and their positioning indicates certain academic maturity on the part of the learners. Learners are expected to follow the semester-wise schedule of courses given in the syllabus.

The lateral entry students shall get 52 credit points transferred from their D. Pharm program. Such students shall take up additional remedial courses of 'Communication Skills' (Theory and Practical) and 'Computer Applications in Pharmacy' (Theory and Practical) equivalent to 3 and 4 credit points respectively, a total of 7 credit points to attain 59 credit points, the maximum of I and II semesters.

8. Academic work

A regular record of attendance both in Theory and Practical shall be maintained by the teaching staff of respective courses.

9. Course of study

The course of study for B. Pharm shall include Semester Wise Theory & Practical as given in Table – I to VIII. The number of hours to be devoted to each theory, tutorial and practical course in any semester shall not be less than that shown in Table – I to VIII.

Table-I: Course of study for semester I

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP101T	Human Anatomy and Physiology I– Theory	3	1	4
BP102T	Pharmaceutical Analysis I – Theory	3	1	4
BP103T	Pharmaceutics I – Theory	3	1	4
BP104T	Pharmaceutical Inorganic Chemistry – Theory	3	1	4
BP105T	Communication skills – Theory *	2	-	2
BP106RBT BP106RMT	Remedial Biology/ Remedial Mathematics – Theory*	2	-	2
BP107P	Human Anatomy and Physiology – Practical	4	-	2
BP108P	Pharmaceutical Analysis I – Practical	4	-	2
BP109P	Pharmaceutics I – Practical	4	-	2
BP110P	Pharmaceutical Inorganic Chemistry – Practical	4	-	2
BP111P	Communication skills – Practical*	2	-	1
BP112RBP	Remedial Biology – Practical*	2	-	1
	Total	**32/34$/36#**	**4**	**27/29$/30#**

#Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB)course.

$Applicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM)course.

* Non University Examination (NUE)

Table-II: Course of study for semester II

Course Code	Name of the course	No. of hours	Tutorial	Credit points
BP201T	Human Anatomy and Physiology II – Theory	3	1	4
BP202T	Pharmaceutical Organic Chemistry I – Theory	3	1	4
BP203T	Biochemistry – Theory	3	1	4
BP204T	Pathophysiology – Theory	3	1	4
BP205T	Computer Applications in Pharmacy – Theory *	3	-	3
BP206T	Environmental sciences – Theory *	3	-	3
BP207P	Human Anatomy and Physiology II –Practical	4	-	2
BP208P	Pharmaceutical Organic Chemistry I– Practical	4	-	2
BP209P	Biochemistry – Practical	4	-	2
BP210P	Computer Applications in Pharmacy – Practical*	2	-	1
	Total	**32**	**4**	**29**

*Non University Examination (NUE)

Table-III: Course of study for semester III

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP301T	Pharmaceutical Organic Chemistry II – Theory	3	1	4
BP302T	Physical Pharmaceutics I – Theory	3	1	4
BP303T	Pharmaceutical Microbiology – Theory	3	1	4
BP304T	Pharmaceutical Engineering – Theory	3	1	4
BP305P	Pharmaceutical Organic Chemistry II – Practical	4	-	2
BP306P	Physical Pharmaceutics I – Practical	4	-	2
BP307P	Pharmaceutical Microbiology – Practical	4	-	2
BP 308P	Pharmaceutical Engineering –Practical	4	-	2
	Total	**28**	**4**	**24**

Table-IV: Course of study for semester IV

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP401T	Pharmaceutical Organic Chemistry III– Theory	3	1	4
BP402T	Medicinal Chemistry I – Theory	3	1	4
BP403T	Physical Pharmaceutics II – Theory	3	1	4
BP404T	Pharmacology I – Theory	3	1	4
BP405T	Pharmacognosy and Phytochemistry I– Theory	3	1	4
BP406P	Medicinal Chemistry I – Practical	4	-	2
BP407P	Physical Pharmaceutics II – Practical	4		2
BP408P	Pharmacology I – Practical	4	-	2
BP409P	Pharmacognosy and Phytochemistry I – Practical	4	-	2
	Total	**31**	**5**	**28**

Table-V: Course of study for semester V

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP501T	Medicinal Chemistry II – Theory	3	1	4
BP502T	Industrial PharmacyI– Theory	3	1	4
BP503T	Pharmacology II – Theory	3	1	4
BP504T	Pharmacognosy and Phytochemistry II– Theory	3	1	4
BP505T	Pharmaceutical Jurisprudence – Theory	3	1	4
BP506P	Industrial PharmacyI – Practical	4	-	2
BP507P	Pharmacology II – Practical	4	-	2
BP508P	Pharmacognosy and Phytochemistry II – Practical	4	-	2
	Total	**27**	**5**	**26**

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Table-VI: Course of study for semester VI

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP601T	Medicinal Chemistry III – Theory	3	1	4
BP602T	Pharmacology III – Theory	3	1	4
BP603T	Herbal Drug Technology – Theory	3	1	4
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	3	1	4
BP605T	Pharmaceutical Biotechnology – Theory	3	1	4
BP606T	Quality Assurance –Theory	3	1	4
BP607P	Medicinal chemistry III – Practical	4	-	2
BP608P	Pharmacology III – Practical	4	-	2
BP609P	Herbal Drug Technology – Practical	4	-	2
	Total	**30**	**6**	**30**

Table-VII: Course of study for semester VII

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP701T	Instrumental Methods of Analysis – Theory	3	1	4
BP702T	Industrial PharmacyII – Theory	3	1	4
BP703T	Pharmacy Practice – Theory	3	1	4
BP704T	Novel Drug Delivery System – Theory	3	1	4
BP705P	Instrumental Methods of Analysis – Practical	4	-	2
BP706PS	Practice School*	12	-	6
	Total	**28**	**5**	**24**

* Non University Examination (NUE)

Table-VIII: Course of study for semester VIII

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP801T	Biostatistics and Research Methodology	3	1	4
BP802T	Social and Preventive Pharmacy	3	1	4
BP803ET	**Elective – 1**			
I	Pharmaceutical Marketing			
II	Pharmaceutical Regulatory Science			
III	Pharmacovigilance			
IV	Quality Control and Standardizations of Herbals	3	1	4
V	Computer Aided Drug Design			
BP804ET	**Elective – 2**			
I	Cell and Molecular Biology			
II	Cosmetic Science	3	1	4
III	Experimental Pharmacology			
IV	Advanced Instrumentation Techniques			
V	Dietary Supplements and Nutraceuticals			
BP805PW	Project Work	12	-	6
	Total	**24**	**4**	**22**

Table-IX: Semester wise credits distribution

Semester	Credit Points
I	**27/29$/30#**
II	29
III	24
IV	28
V	26
VI	30
VII	24
VIII	22
Extracurricular/ Co curricular activities	01*
Total credit points for the program	**211/213$/214#**

* The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University. The criteria to acquire this credit point shall be defined by the university from time to time.

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#Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology course.

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10. Program Committee

1. The B. Pharm. program shall have a Program Committee constituted by the Head of the institution in consultation with all the Heads of the departments.

2. The composition of the Program Committee shall be as follows:

   A senior teacher shall be the Chairperson; One Teacher from each department handling B.Pharm courses; and four student representatives of the program (one from each academic year), nominated by the Head of the institution.

3. Duties of the Program Committee:

   i. Periodically reviewing the progress of the classes.
   ii. Discussing the problems concerning curriculum, syllabus and the conduct of classes.
   iii. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.
   iv. Communicating its recommendation to the Head of the institution on academic matters.
   v. The Program Committee shall meet at least thrice in a semester preferably at the end of each Sessionalexam (Internal Assessment) and before the end semester exam.

11. Examinations/Assessments

The scheme for internal assessment and end semester examinations is given in Table – X.

End semester examinations

The End Semester Examinations for each theory and practical coursethrough semesters I to VIII shall beconducted by the university except for the subjects with asterix symbol (*) in table I and II for which examinations shall be conducted by the subject experts at college level and the marks/grades shall be submitted to the university.

Tables-X: Schemes for internal assessments and end semester examinations semester wise

Semester I

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP101T	Human Anatomy and Physiology I– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP102T	Pharmaceutical Analysis I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP103T	Pharmaceutics I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP104T	Pharmaceutical Inorganic Chemistry – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP105T	Communication skills – Theory *	5	10	1 Hr	15	35	1.5 Hrs	50
BP106RBT BP106RMT	Remedial Biology/ Mathematics – Theory*	5	10	1 Hr	15	35	1.5 Hrs	50
BP107P	Human Anatomy and Physiology – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP108P	Pharmaceutical Analysis I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP109P	Pharmaceutics I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP110P	Pharmaceutical Inorganic Chemistry – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP111P	Communication skills – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
BP112RBP	Remedial Biology – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
	Total	**70/75$/80#**	**115/125$/130#**	**23/24$/26# Hrs**	**185/200$/210#**	**490/525$/540#**	**31.5/33$/35# Hrs**	**675/725$/750#**

#Applicable ONLY for the students studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB)course.

$Applicable ONLY for the students studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM)course.

* Non University Examination(NUE)

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Semester II

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP201T	Human Anatomy and Physiology II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP202T	Pharmaceutical Organic Chemistry I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP203T	Biochemistry – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP204T	Pathophysiology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP205T	Computer Applications in Pharmacy – Theory*	10	15	1 Hr	25	50	2 Hrs	75
BP206T	Environmental sciences – Theory*	10	15	1 Hr	25	50	2 Hrs	75
BP207P	Human Anatomy and Physiology II –Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP208P	Pharmaceutical Organic Chemistry I– Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP209P	Biochemistry – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP210P	Computer Applications in Pharmacy – Practical*	5	5	2 Hrs	10	15	2 Hrs	25
	Total	**80**	**125**	**20 Hrs**	**205**	**520**	**30 Hrs**	**725**

* The subject experts at college level shall conduct examinations

Semester III

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP301T	Pharmaceutical Organic Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP302T	PhysicalPharmaceuticsI –Theory	10	15	1 Hr	25	75	3 Hrs	100
BP303T	Pharmaceutical Microbiology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP304T	Pharmaceutical Engineering – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP305P	Pharmaceutical Organic Chemistry II – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP306P	Physical Pharmaceutics I – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP307P	Pharmaceutical Microbiology – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP308P	Pharmaceutical Engineering – Practical	5	10	4 Hr	15	35	4 Hrs	50
Total		**60**	**100**	**20**	**160**	**440**	**28Hrs**	**600**

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Semester IV

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP401T	Pharmaceutical Organic Chemistry III– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP402T	Medicinal Chemistry I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP403T	Physical Pharmaceutics II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP404T	Pharmacology I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP405T	Pharmacognosy I – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP406P	Medicinal Chemistry I – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP407P	Physical Pharmaceutics II – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP408P	Pharmacology I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP409P	Pharmacognosy I – Practical	5	10	4 Hrs	15	35	4 Hrs	50
Total		**70**	**115**	**21 Hrs**	**185**	**515**	**31 Hrs**	**700**

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Semester V

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP501T	Medicinal Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP502T	Industrial PharmacyI– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP503T	Pharmacology II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP504T	Pharmacognosy II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP505T	Pharmaceutical Jurisprudence – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP506P	Industrial PharmacyI– Practical	5	10	4 Hr	15	35	4 Hrs	50
BP507P	Pharmacology II – Practical	5	10	4 Hr	15	35	4 Hrs	50
BP508P	Pharmacognosy II – Practical	5	10	4 Hr	15	35	4 Hrs	50
	Total	**65**	**105**	**17 Hr**	**170**	**480**	**27 Hrs**	**650**

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Semester VI

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP601T	Medicinal Chemistry III – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP602T	Pharmacology III – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP603T	Herbal Drug Technology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP605T	Pharmaceutical Biotechnology– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP606T	Quality Assurance– Theory	10	15	1 Hr	25	75	3 Hrs	100
BP607P	Medicinal chemistry III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP608P	Pharmacology III – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP609P	Herbal Drug Technology – Practical	5	10	4 Hrs	15	35	4 Hrs	50
	Total	**75**	**120**	**18 Hrs**	**195**	**555**	**30 Hrs**	**750**

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Semester VII

Course code	Name of the course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP701T	Instrumental Methods of Analysis – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP702T	Industrial Pharmacy – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP703T	Pharmacy Practice – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP704T	Novel Drug Delivery System – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP705 P	Instrumental Methods of Analysis – Practical	5	10	4 Hrs	15	35	4 Hrs	50
BP706 PS	Practice School*	25	-	-	25	125	5 Hrs	150
Total		**70**	**70**	**8Hrs**	**140**	**460**	**21 Hrs**	**600**

* The subject experts at college level shall conduct examinations

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Semester VIII

Course code	Name of the course	Internal Assessment				End Semester Exams		Total
		Continuous Mode	Sessional Exams		Total	Marks	Duration	Marks
			Marks	Duration				
BP801T	Biostatistics and Research Methodology – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP802T	Social and Preventive Pharmacy – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP803E	**Elective -1**	10	15	1 Hr	25	75	3 Hrs	100
I	Pharmaceutical Marketing – Theory							
II	Pharmaceutical Regulatory Science – Theory							
III	Pharmacovigilance – Theory							
IV	Quality Control and Standardizations of Herbals – Theory							
V	Computer Aided Drug Design – Theory							
BP804ET	**Elective – 2**	10	15	1 Hr	25	75	3 Hrs	100
I	Cell and Molecular Biology – Theory							
II	Cosmetic Science – Theory							
III	Experimental Pharmacology – Theory							
IV	Advanced Instrumentation Techniques – Theory							
V	Dietary Supplements and Nutraceuticals - Theory							
BP805PW	Project Work	-	-	-	-	150	4 Hrs	150
	Total	**40**	**60**	**4 Hrs**	**100**	**450**	**16 Hrs**	**550**

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Internal assessment: Continuous mode

The marks allocated for Continuous mode of Internal Assessment shall be awarded as per the scheme given below.

Table-XI:Scheme for awarding internal assessment: Continuous mode

Theory		
Criteria	**Maximum Marks**	
Attendance (Refer Table – XII)	4	2
Academic activities (Average of any 3 activities e.g. quiz, assignment, open book test, field work, group discussion and seminar)	3	1.5
Student – Teacher interaction	3	1.5
Total	**10**	**5**
Practical		
Attendance (Refer Table – XII)	2	
Based on Practical Records, Regular viva voce, etc.	3	
Total	**5**	

Table- XII: Guidelines for the allotment of marks for attendance

Percentage of Attendance	Theory	Practical
95 – 100	4	2
90 – 94	3	1.5
85 – 89	2	1
80 – 84	1	0.5
Less than 80	0	0

Sessional Exams

Two Sessional exams shall be conducted for each theory / practical course as per the schedule fixed by the college(s). The scheme of question paper for theory and practical Sessional examinations is given below. The average marks of two Sessional exams shall be computed for internal assessment as per the requirements given in tables – X.

Sessional exam shall be conducted for 30 marks for theory and shall be computed for 15 marks. Similarly Sessional exam for practical shall be conducted for 40 marks and shall be computed for 10 marks.

Question paper pattern for theory Sessional examinations

For subjects having University examination

I. Multiple Choice Questions (MCQs)	=	10 x 1 = 10
OR		OR
Objective Type Questions (5 x 2)	=	05 x 2 = 10
(Answer all the questions)		
I. Long Answers (Answer 1 out of 2)	=	1 x 10 = 10
II. Short Answers (Answer 2 out of 3)	=	2 x 5 = 10
	Total =	30 marks

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For subjects having Non University Examination

I. Long Answers (Answer 1 out of 2)	=	1 x 10 = 10
II. Short Answers (Answer 4 out of 6)	=	4 x 5 = 20
Total	=	30 marks

Question paper pattern for practical sessional examinations

I. Synopsis	=	10
II. Experiments	=	25
III. Viva voce	=	05
Total	=	40 marks

12. Promotion and award of grades

A student shall be declared PASSand eligible for getting gradein a course of B.Pharm.program if he/she secures at least 50% marks in that particular course including internal assessment.For example, to be declared as PASS and to get grade, the student has to secure a minimum of 50 marks for the total of 100 including continuous mode of assessment and end semester theory examination and has to secure a minimum of 25 marks for the total 50 including internal assessment and end semester practical examination.

13. Carry forward of marks

In case a studentfails to secure the minimum 50% in any Theory or Practical course as specified in 12,then he/she shall reappear for the end semester examinationof that course. However his/her marks of the Internal Assessmentshallbe carried overand he/she shall be entitled for grade obtained by him/her on passing.

14. Improvement of internal assessment

A studentshall have the opportunity to improvehis/her performance only oncein the Sessional exam component of the internal assessment. The re-conduct of the Sessional exam shall be completed before the commencement of next end semester theory examinations.

15. Re-examination of end semester examinations

Reexamination ofend semester examinationshall be conducted as per the schedule given in table XIII. The exact dates of examinations shall be notified from time to time.

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Table-XIII: Tentative schedule of end semester examinations

Semester	For Regular Candidates	For Failed Candidates
I, III, V and VII	November / December	May / June
II, IV, VI and VIII	May / June	November / December

Question paper pattern for end semester theory examinations

For 75 marks paper

I. Multiple Choice Questions(MCQs)	=	20 x 1 = 20
OR		OR
Objective Type Questions (10 x 2)	=	10 x 2 = 20
(Answer all the questions)		
II. Long Answers (Answer 2 out of 3)	=	2 x 10 = 20
III. Short Answers (Answer 7 out of 9)	=	7 x 5 = 35
Total	=	75 marks

For 50 marks paper

I. Long Answers (Answer 2 out of 3)	=	2 x 10 = 20
II. Short Answers (Answer 6 out of 8)	=	6 x 5 = 30
Total	=	50 marks

For 35 marks paper

I. Long Answers (Answer 1 out of 2)	=	1 x 10 = 10
II. Short Answers (Answer 5 out of 7)	=	5 x 5 = 25
Total	=	35 marks

Question paper pattern for end semester practical examinations

I. Synopsis	=	5
II. Experiments	=	25
III. Viva voce	=	5
Total	=	35 marks

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16. Academic Progression:

No student shall be admitted to any examination unless he/she fulfills the norms given in 6. Academic progression rules are applicable as follows:

A student shall be eligible to carry forward all the courses of I, II and III semesters till the IV semester examinations. However, he/she shall not be eligible to attend the courses of V semester until all the courses of I and II semesters are successfully completed.

A student shall be eligible to carry forward all the courses of III, IV and V semesters till the VI semester examinations. However, he/she shall not be eligible to attend the courses of VII semester until all the courses of I, II, III and IV semesters are successfully completed.

A student shall be eligible to carry forward all the courses of V, VI and VII semesters till the VIII semester examinations. However, he/she shall not be eligible to get the course completion certificate until all the courses of I, II, III, IV, V and VI semesters are successfully completed.

A student shall be eligible to get his/her CGPA upon successful completion of the courses of I to VIII semesters within the stipulated time period as per the norms specified in 26.

A lateral entry student shall be eligible to carry forward all the courses of III, IV and V semesters till the VI semester examinations. However, he/she shall not be eligible to attend the courses of VII semester until all the courses of III and IV semesters are successfully completed.

A lateral entry student shall be eligible to carry forward all the courses of V, VI and VII semesters till the VIII semester examinations. However, he/she shall not be eligible to get the course completion certificate until all the courses of III, IV, V and VI semesters are successfully completed.

A lateral entry student shall be eligible to get his/her CGPA upon successful completion of the courses of III to VIII semesters within the stipulated time period as per the norms specified in 26.

Any student who hasgiven more than 4 chances for successful completion of I / III semester courses and more than 3 chances for successful completion of II / IV semester courses shall be permitted to attend V / VII semester classes ONLY during the subsequent academic year as the case may be. In simpler terms there shall NOT be any ODD BATCH for any semester.

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Note: Grade ABshould be considered as failed and treated as one head for deciding academic progression. Such rules are also applicable for those students who fail to register for examination(s) of any course in anysemester.

17. Grading of performances

Letter grades and grade points allocations:

Based on the performances, each student shall be awarded a final letter grade at the end of the semester for each course.The letter grades and their corresponding grade points are given in Table – XII.

Table – XII: Letter grades and grade points equivalent to Percentage of marks and performances

Percentage of Marks Obtained	Letter Grade	Grade Point	Performance
90.00 – 100	O	10	Outstanding
80.00 – 89.99	A	9	Excellent
70.00 – 79.99	B	8	Good
60.00 – 69.99	C	7	Fair
50.00 – 59.99	D	6	Average
Less than 50	F	0	Fail
Absent	AB	0	Fail

A learner who remains absent for any end semester examination shall be assigned a letter grade of ABand a corresponding grade point of zero. He/she should reappear for the said evaluation/examination in due course.

18. The Semester grade point average (SGPA)

The performance of a student in a semester is indicated by a number called 'Semester Grade Point Average' (SGPA). The SGPA is the weighted average of the grade points obtainedin all the courses by the student during the semester. For example, if a student takes five courses(Theory/Practical) in a semester with credits C1, C2, C3, C4 and C5 and the student's grade pointsin these courses are G1, G2, G3, G4 and G5, respectively, and then students' SGPA is equal to:

$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4G_4 + C_5G_5}{C_1 + C_2 + C_3 + C_4 + C_5}$$

The SGPA is calculated to two decimal points.It should be noted that, the SGPA for any semester shall take into consideration the F and ABSgrade awarded in that semester. For example if a learner has a F or ABS grade in course 4, theSGPA shall then be computed as:

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$$SGPA = \frac{C_1G_1 + C_2G_2 + C_3G_3 + C_4 * ZERO + C_5G_5}{C_1 + C_2 + C_3 + C_4 + C_5}$$

19. Cumulative Grade Point Average (CGPA)

The CGPA is calculated with the SGPA of all the VIII semesters to two decimal points and is indicated in final grade report card/final transcript showing the grades of all VIII semesters and their courses. The CGPA shall reflect the failed statusin case of F grade(s),till the course(s) is/are passed. When the course(s)is/are passedby obtaining a pass grade on subsequent examination(s) theCGPA shall only reflect the new grade and not the fail grades earned earlier.The CGPA is calculated as:

$$CGPA = \frac{C_1S_1 + C_2S_2 + C_3S_3 + C_4S_4 + C_5S_5 + C_6S_6 + C_7S_7 + C_8S_8}{C_1 + C_2 + C_3 + C_4 + C_5 + C_6 + C_7 + C_8}$$

where $C_1, C_2, C_3, \ldots$ is the total number of credits for semester I,II,III,.... and $S_1, S_2, S_3, \ldots$ is the SGPA of semester I,II,III,.... .

20. Declaration of class

The class shall be awarded on the basis of CGPA as follows:

First Class with Distinction	= CGPA of. 7.50 and above
First Class	= CGPA of 6.00 to 7.49
Second Class	= CGPA of 5.00 to 5.99

21. Project work

All the students shall undertake a projectunder the supervision of a teacher and submit a report. The area of the project shall directly relate any one of the elective subject opted by the student in semester VIII. The project shall be carried out in group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages).

The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of five students). The projects shall be evaluated as per the criteria given below.

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Evaluation of Dissertation Book:

Objective(s) of the work done	15 Marks
Methodology adopted	20 Marks
Results and Discussions	20 Marks
Conclusions and Outcomes	20 Marks
Total	**75 Marks**

Evaluation of Presentation:

Presentation of work	25 Marks
Communication skills	20 Marks
Question and answer skills	30 Marks
Total	**75 Marks**

Explanation: The 75 marks assigned to the dissertation book shall be same for all the students in a group. However, the 75 marks assigned for presentation shall be awarded based on the performance of individual students in the given criteria.

22. Industrial training (Desirable)

Every candidate shall be required to work for at least 150 hours spread over four weeks in a Pharmaceutical Industry/Hospital. It includes Production unit, Quality Control department, Quality Assurance department, Analytical laboratory, Chemical manufacturing unit, Pharmaceutical R&D, Hospital (Clinical Pharmacy), Clinical Research Organization, Community Pharmacy, etc. After the Semester – VI and before the commencement of Semester – VII, and shall submit satisfactory report of such work and certificate duly signed by the authority of training organization to the head of the institute.

23. Practice School

In the VII semester, every candidate shall undergo practice school for a period of 150 hours evenly distributed throughout the semester. The student shall opt any one of the domains for practice school declared by the program committee from time to time.

At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). Along with the exams of semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the subject experts at college leveland grade point shall be awarded.

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24. Award of Ranks

Ranks and Medals shall be awarded on the basis of final CGPA. However, candidates who fail in one or more courses during the B.Pharm program shall not be eligible for award of ranks.Moreover, the candidates should have completed the B. Pharm program in minimum prescribed number of years, (four years) for the award of Ranks.

25. Award of degree

Candidates who fulfill the requirements mentioned above shall be eligible for award of degree during the ensuing convocation.

26. Duration for completion of the program of study

The duration for the completion of the program shall be fixed as double the actual duration of the program and the students have to pass within the said period, otherwise they have to get fresh Registration.

27. Re-admission after break of study

Candidate who seeks re-admission to the program after break of study has to get the approval from the university by paying a condonation fee.

No condonation is allowed for the candidate who has more than 2 years of break up period and he/she has to rejoin the program by paying the required fees.

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CHAPTER - II: SYLLABUS

Semester I

BP101T. HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives: Upon completion of this course the student should be able to

1. Explain the gross morphology, structure and functions of various organs of the human body.
2. Describe the various homeostatic mechanisms and their imbalances.
3. Identify the various tissues and organs of different systems of human body.
4. Perform the various experiments related to special senses and nervous system.
5. Appreciate coordinated working pattern of different organs of each system

Course Content:

Unit I **10 hours**

- **Introduction to human body**
  Definition and scope of anatomy and physiology, levels of structural organization and body systems, basic life processes, homeostasis, basic anatomical terminology.
- **Cellular level of organization**
  Structure and functions of cell, transport across cell membrane, cell division, cell junctions. General principles of cell communication, intracellular signaling pathway activation by extracellular signal molecule, Forms of intracellular signaling: a) Contact-dependent b) Paracrine c) Synaptic d) Endocrine
- **Tissue level of organization**
  Classification of tissues, structure, location and functions of epithelial, muscular and nervous and connective tissues.

Unit II **10 hours**

- **Integumentary system**
  Structure and functions of skin
- **Skeletal system**
  Divisions of skeletal system, types of bone, salient features and functions of bones of axial and appendicular skeletal system
  Organization of skeletal muscle, physiology of muscle contraction, neuromuscular junction

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- **Joints**
  Structural and functional classification, types of joints movements and its articulation

Unit III **10 hours**

- **Body fluids and blood**
- Body fluids, composition and functions of blood, hemopoeisis, formation of hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance and disorders of blood, Reticulo endothelial system.
- **Lymphatic system**

  Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of lymphatic system

Unit IV **08 hours**

Peripheral nervous system:
Classification of peripheral nervous system: Structure and functions of sympathetic and parasympathetic nervous system.
Origin and functions of spinal and cranial nerves.

- **Special senses**
  Structure and functions of eye, ear, nose and tongue and their disorders.

Unit V **07 hours**

- **Cardiovascular system**
  Heart – anatomy of heart, blood circulation, blood vessels, structure and functions of artery, vein and capillaries, elements of conduction system of heart and heart beat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram and disorders of heart.

BP107P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject.

1. Study of compound microscope.
2. Microscopic study of epithelial and connective tissue
3. Microscopic study of muscular and nervous tissue
4. Identification of axial bones
5. Identification of appendicular bones

6. Introduction to hemocytometry.
7. Enumeration of white blood cell (WBC) count
8. Enumeration of total red blood corpuscles (RBC) count
9. Determination of bleeding time
10. Determination of clotting time
11. Estimation of hemoglobin content
12. Determination of blood group.
13. Determination of erythrocyte sedimentation rate (ESR).
14. Determination of heart rate and pulse rate.
15. Recording of blood pressure.

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA
4. Text book of Medical Physiology- Arthur C,Guyton andJohn.E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.

6. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books (Latest Editions)

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

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BP102T. PHARMACEUTICAL ANALYSIS (Theory)

45 Hours

Scope: This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs

Objectives: Upon completion of the course student shall be able to

- understand the principles of volumetric and electro chemical analysis
- carryout various volumetric and electrochemical titrations
- develop analytical skills

Course Content:

UNIT-I **10 Hours**

(a) Pharmaceutical analysis- Definition and scope

i) Different techniques of analysis

ii) Methods of expressing concentration

iii) Primary and secondary standards.

iv) Preparation and standardization of various molar and normal solutions- Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate

(b) Errors: Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures

(c) Pharmacopoeia, Sources of impurities in medicinal agents,limit tests.

UNIT-II **10 Hours**

- **Acid base titration**: Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, and very weak acids and bases, neutralization curves
- **Non aqueous titration**: Solvents, acidimetry and alkalimetry titration and estimation of Sodium benzoate and Ephedrine HCl

UNIT-III **10 Hours**

- **Precipitation titrations**: Mohr's method, Volhard's, Modified Volhard's, Fajans method, estimation of sodium chloride.
- **Complexometric titration**: Classification, metal ion indicators, masking and demasking reagents, estimation of Magnesium sulphate, and calcium gluconate.
- **Gravimetry**: Principle and steps involved in gravimetric analysis. Purity of the precipitate: co-precipitation and post precipitation, Estimation of barium sulphate.
- Basic Principles,methods and application of diazotisation titration.

UNIT-IV **08 Hours**

Redox titrations

(a) Concepts of oxidation and reduction

(b) Types of redox titrations (Principles and applications)

Cerimetry, Iodimetry, Iodometry, Bromatometry, Dichrometry, Titration with potassium iodate

UNIT-V **07 Hours**

- **Electrochemical methods of analysis**
  - **Conductometry**- Introduction, Conductivity cell, Conductometric titrations, applications.
  - **Potentiometry** - Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications.
  - **Polarography** - Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications

BP108P. PHARMACEUTICAL ANALYSIS (Practical)

4 Hours / Week

I Limit Test of the following

(1) Chloride
(2) Sulphate
(3) Iron
(4) Arsenic

II Preparation and standardization of

(1) Sodium hydroxide
(2) Sulphuric acid
(3) Sodium thiosulfate
(4) Potassium permanganate
(5) Ceric ammonium sulphate

III Assay of the following compounds along with Standardization of Titrant

(1) Ammonium chloride by acid base titration
(2) Ferrous sulphate by Cerimetry
(3) Copper sulphate by Iodometry
(4) Calcium gluconate by complexometry
(5) Hydrogen peroxide by Permanganometry
(6) Sodium benzoate by non-aqueous titration
(7) Sodium Chloride by precipitation titration

IV Determination of Normality by electro-analytical methods

(1) Conductometric titration of strong acid against strong base
(2) Conductometric titration of strong acid and weak acid against strong base
(3) Potentiometric titration of strong acid against strong base

Recommended Books: (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry
4. Bentley and Driver's Textbook of Pharmaceutical Chemistry
5. John H. Kennedy, Analytical chemistry principles
6. Indian Pharmacopoeia.

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BP103T. PHARMACEUTICS- I (Theory)

45 Hours

Scope: This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.

Objectives: Upon completion of this course the student should be able to:

- Know the history of profession of pharmacy
- Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations
- Understand the professional way of handling the prescription
- Preparation of various conventional dosage forms

Course Content:

UNIT – I **10 Hours**

- **Historical background and development of profession of pharmacy**: History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia.
- **Dosage forms:** Introduction to dosage forms, classification and definitions
- **Prescription:** Definition, Parts of prescription, handling of Prescription and Errors in prescription.
- **Posology:** Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

UNIT – II **10 Hours**

- **Pharmaceutical calculations**: Weights and measures – Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight.

- **Powders:** Definition, classification, advantages and disadvantages,Simple & compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.

- **Liquid dosage forms:** Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques

UNIT – III **08 Hours**

- **Monophasic liquids:** Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.
- **Biphasic liquids:**
- **Suspensions:** Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.
- **Emulsions:** Definition, classification, emulsifying agent, test for the identification of type ofEmulsion, Methods of preparation & stability problems and methods to overcome.

UNIT – IV **08 Hours**

- **Suppositories**: Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.
- **Pharmaceutical incompatibilities**: Definition, classification, physical, chemical and therapeutic incompatibilities with examples.

UNIV – V **07 Hours**

- **Semisolid dosage forms:** Definitions, classification, mechanisms and factors influencing dermal penetration of drugs. Preparation of ointments, pastes, creams and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid dosages forms

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BP109P. PHARMACEUTICSI (Practical)

3 Hours / week

1 . Syrups

a) Syrup IP'66

b) Compound syrup of Ferrous Phosphate BPC'68

2. Elixirs a) Piperazine citrate elixir

b) Paracetamol pediatric elixir

3.Linctus a) Terpin Hydrate Linctus IP'66

b) Iodine Throat Paint (Mandles Paint)

4. Solutions

a) Strong solution of ammonium acetate

b) Cresol with soap solution

c) Lugol's solution

5. Suspensions

a) Calamine lotion

b) Magnesium Hydroxide mixture

c) Aluminimum Hydroxide gel

6. Emulsions a) Turpentine Liniment

b) Liquid paraffin emulsion

7. Powders and Granules

a) ORS powder (WHO)

b) Effervescent granules

c)Dusting powder

d)Divded powders

8. Suppositories

a) Glycero gelatin suppository

b) Coca butter suppository

c) Zinc Oxide suppository

8. Semisolids

a) Sulphur ointment

b) Non staining-iodine ointment with methyl salicylate

c) Carbopal gel

9. Gargles and Mouthwashes

a) Iodine gargle

b) Chlorhexidine mouthwash

Recommended Books: (Latest Editions)

1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.
2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi.
3. M.E. Aulton, Pharmaceutics, The Science& Dosage Form Design, Churchill Livingstone, Edinburgh.
4. Indian pharmacopoeia.
5. British pharmacopoeia.
6. Lachmann. Theory and Practice of Industrial Pharmacy,Lea& Febiger Publisher, The University of Michigan.
7. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.
8. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publications, New Delhi.
9. E.A. Rawlins, Bentley's Text Book of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.
10. Isaac Ghebre Sellassie: Pharmaceutical Pelletization Technology, Marcel Dekker, INC, New York.
11. Dilip M. Parikh: Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC, New York.
12. Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.

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BP104T. PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)

45 Hours

Scope: This subject deals with the monographs of inorganic drugs and pharmaceuticals.

Objectives: Upon completion of course student shall be able to

- know the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals
- understand the medicinal and pharmaceutical importance of inorganic compounds

Course Content:

UNIT I **10 Hours**

- **Impurities in pharmaceutical substances:** History of Pharmacopoeia, Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate

  General methods of preparation, assay for the compounds superscripted with **asterisk (*)**, properties and medicinal uses of inorganic compounds belonging to the following classes

UNIT II **10 Hours**

- **Acids, Bases and Buffers:** Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity.
- **Major extra and intracellular electrolytes**: Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride*, Potassium chloride, Calcium gluconate* and Oral Rehydration Salt (ORS), Physiological acid base balance.
- **Dental products**: Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement.

UNIT III **10 Hours**

- **Gastrointestinal agents**

  Acidifiers: Ammonium chloride* and Dil. HCl

  Antacid: Ideal properties of antacids, combinations of antacids, Sodium

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Bicarbonate*, Aluminum hydroxide gel, Magnesium hydroxide mixture

Cathartics: Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite

Antimicrobials: Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide*, Chlorinated lime*, Iodine and its preparations

UNIT IV **08 Hours**

- **Miscellaneous compounds**

  Expectorants: Potassium iodide, Ammonium chloride*.

  Emetics: Copper sulphate*, Sodium potassium tartarate

  Haematinics: Ferrous sulphate*, Ferrous gluconate

  Poison and Antidote: Sodium thiosulphate*, Activated charcoal, Sodium nitrite333

  Astringents: Zinc Sulphate, Potash Alum

UNIT V **07 Hours**

- **Radiopharmaceuticals**: Radio activity, Measurement of radioactivity, Properties of α, β, γ radiations, Half life, radio isotopes and study of radio isotopes - Sodium iodide I^{131}, Storage conditions, precautions & pharmaceutical application of radioactive substances.

BP110P. PHARMACEUTICAL INORGANIC CHEMISTRY (Practical)

4 Hours / Week

I **Limit tests for following ions**
- Limit test for Chlorides and Sulphates
- Modified limit test for Chlorides and Sulphates
- Limit test for Iron
- Limit test for Heavy metals
- Limit test for Lead
- Limit test for Arsenic

II **Identification test**
- Magnesium hydroxide
- Ferrous sulphate
- Sodium bicarbonate
- Calcium gluconate
- Copper sulphate

III **Test for purity**
- Swelling power of Bentonite
- Neutralizing capacity of aluminum hydroxide gel
- Determination of potassium iodate and iodine in potassium Iodide

IV **Preparation of inorganic pharmaceuticals**
- Boric acid
- Potash alum
- Ferrous sulphate

Recommended Books (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 4th edition.
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry, 3rd Edition
4. M.L Schroff, Inorganic Pharmaceutical Chemistry
5. Bentley and Driver's Textbook of Pharmaceutical Chemistry
6. Anand & Chatwal, Inorganic Pharmaceutical Chemistry
7. Indian Pharmacopoeia

BP105T.COMMUNICATION SKILLS (Theory)

30 Hours

Scope: This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business.

Objectives:

Upon completion of the course the student shall be able to

1. Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation
2. Communicate effectively (Verbal and Non Verbal)
3. Effectively manage the team as a team player
4. Develop interview skills
5. Develop Leadership qualities and essentials

Course content:

UNIT – I **07 Hours**

- **Communication Skills:** Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context
- **Barriers to communication:** Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers
- **Perspectives in Communication:** Introduction, Visual Perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment

UNIT – II **07 Hours**

- **Elements of Communication:** Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication
- **Communication Styles:** Introduction, The Communication Styles Matrix with example for each -Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style

UNIT – III **07 Hours**

- **Basic Listening Skills:** Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations
- **Effective Written Communication:** Introduction, When and When Not to Use Written Communication - Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication
- **Writing Effectively:** Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message

UNIT – IV **05 Hours**

- **Interview Skills:** Purpose of an interview, Do's and Dont's of an interview
- **Giving Presentations:** Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery

UNIT – V **04 Hours**

- **Group Discussion:** Introduction, Communication skills in group discussion, Do's and Dont's of group discussion

BP111P.COMMUNICATION SKILLS (Practical)

2 Hours / week

Thefollowing learning modules are to be conducted using wordsworth® English language lab software

Basic communication covering the following topics

Meeting People

Asking Questions

Making Friends

What did you do?

Do's and Dont's

Pronunciations covering the following topics

Pronunciation (Consonant Sounds)

Pronunciation and Nouns

Pronunciation (Vowel Sounds)

Advanced Learning

Listening Comprehension / Direct and Indirect Speech

Figures of Speech

Effective Communication

Writing Skills

Effective Writing

Interview Handling Skills

E-Mail etiquette

Presentation Skills

Recommended Books: (Latest Edition)

1. Basic communication skills for Technology, Andreja. J. Ruther Ford, 2nd Edition, Pearson Education, 2011
2. Communication skills, Sanjay Kumar, Pushpalata, 1stEdition, Oxford Press, 2011
3. Organizational Behaviour, Stephen .P. Robbins, 1stEdition, Pearson, 2013
4. Brilliant- Communication skills, Gill Hasson, 1stEdition, Pearson Life, 2011
5. The Ace of Soft Skills: Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5thEdition, Pearson, 2013
6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1st Edition Universe of Learning LTD, 2010
7. Communication skills for professionals, Konar nira, 2ndEdition, New arrivals – PHI, 2011
8. Personality development and soft skills, Barun K Mitra, 1stEdition, Oxford Press, 2011
9. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning india pvt.ltd, 2011
10. Soft skills and professional communication, Francis Peters SJ, 1stEdition, Mc Graw Hill Education, 2011
11. Effective communication, John Adair, 4thEdition, Pan Mac Millan,2009
12. Bringing out the best in people, Aubrey Daniels, 2ndEdition, Mc Graw Hill, 1999

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BP 106RBT.REMEDIAL BIOLOGY (Theory)

30 Hours

Scope: To learn and understand the components of living world, structure and functional system of plant and animal kingdom.

Objectives: Upon completion of the course, the student shall be able to

- know the classification and salient features of five kingdoms of life
- understand the basic components of anatomy & physiology of plant
- know understand the basic components of anatomy & physiology animal with special reference to human

UNIT I — 07 Hours

Living world:

- Definition and characters of living organisms
- Diversity in the living world
- Binomial nomenclature
- Five kingdoms of life and basis of classification. Salient features of Monera, Potista, Fungi, Animalia and Plantae, Virus,

Morphology of Flowering plants

- Morphology of different parts of flowering plants – Root, stem, inflorescence, flower, leaf, fruit, seed.
- General Anatomy of Root, stem, leaf of monocotyledons & Dicotylidones.

UNIT II — 07 Hours

Body fluids and circulation

- Composition of blood, blood groups, coagulation of blood
- Composition and functions of lymph
- Human circulatory system
- Structure of human heart and blood vessels
- Cardiac cycle, cardiac output and ECG

Digestion and Absorption

- Human alimentary canal and digestive glands
- Role of digestive enzymes
- Digestion, absorption and assimilation of digested food

Breathing and respiration

- Human respiratory system
- Mechanism of breathing and its regulation
- Exchange of gases, transport of gases and regulation of respiration
- Respiratory volumes

UNIT III **07 Hours**

Excretory products and their elimination

- Modes of excretion
- Human excretory system- structure and function
- Urine formation
- Rennin angiotensin system

Neural control and coordination

- Definition and classification of nervous system
- Structure of a neuron
- Generation and conduction of nerve impulse
- Structure of brain and spinal cord
- Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata

Chemical coordination and regulation

- Endocrine glands and their secretions
- Functions of hormones secreted by endocrine glands

Human reproduction

- Parts of female reproductive system
- Parts of male reproductive system
- Spermatogenesis and Oogenesis
- Menstrual cycle

UNIT IV **05 Hours**

Plants and mineral nutrition:

- Essential mineral, macro and micronutrients
- Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation

Photosynthesis

- Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affecting photosynthesis.

UNIT V **04 Hours**

Plant respiration: Respiration, glycolysis, fermentation (anaerobic).

Plant growth and development

- Phases and rate of plant growth, Condition of growth,Introduction to plant growth regulators

Cell - The unit of life

- Structure and functions of cell and cell organelles.Cell division

Tissues

- Definition, types of tissues, location and functions.

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Text Books

a. Text book of Biology by S. B. Gokhale
b. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

Reference Books

a. A Text book of Biology by B.V. Sreenivasa Naidu
b. A Text book of Biology by Naidu and Murthy
c. Botany for Degree students By A.C.Dutta.
d.Outlines of Zoology by M. Ekambaranatha ayyer and T. N. Ananthakrishnan.
e. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate

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BP112RBP.REMEDIAL BIOLOGY (Practical)

30 Hours

1. Introduction to experiments in biology
   a) Study of Microscope
   b) Section cutting techniques
   c) Mounting and staining
   d) Permanent slide preparation
2. Study of cell and its inclusions
3. Study of Stem, Root, Leaf, seed, fruit, flower and their modifications
4. Detailed study of frog by using computer models
5. Microscopic study and identification of tissues pertinent to Stem, Root Leaf, seed, fruit and flower
6. Identification of bones
7. Determination of blood group
8. Determination of blood pressure
9. Determination of tidal volume

Reference Books

1. Practical human anatomy and physiology. by S.R.Kale and R.R.Kale.
2. A Manual of pharmaceutical biology practical by S.B.Gokhale, C.K.Kokate and S.P.Shriwastava.
3. Biology practical manual according to National core curriculum .Biology forum of Karnataka. Prof .M.J.H.Shafi

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BP 106RMT.REMEDIAL MATHEMATICS (Theory)

30 Hours

Scope: This is an introductory course in mathematics. This subject deals with the introduction to Partial fraction, Logarithm, matrices and Determinant, Analytical geometry, Calculus, differential equation and Laplace transform.

Objectives: Upon completion of the course the student shall be able to:-

1. Know the theory and their application in Pharmacy
2. Solve the different types of problems by applying theory
3. Appreciate the important application of mathematics in Pharmacy

Course Content:

UNIT – I **06 Hours**

- **Partial fraction**

Introduction, Polynomial, Rational fractions, Proper and Improper fractions, Partial fraction , Resolving into Partial fraction, Application of Partial Fraction in Chemical Kinetics and Pharmacokinetics

- **Logarithms**

Introduction, Definition, Theorems/Properties of logarithms, Common logarithms, Characteristic and Mantissa, worked examples, application of logarithm to solve pharmaceutical problems.

- **Function**:

Real Valued function, Classification of real valued functions,

- **Limits and continuity** :

Introduction , Limit of a function, Definition of limit of a function ($\in$ - δ definition) , $\lim_{x \to a} \frac{x^n - a^n}{x - a} = na^{n-1}$, $\lim_{\theta \to 0} \frac{\sin\theta}{\theta} = 1$,

UNIT –II **06 Hours**

- **Matrices and Determinant:**

Introduction matrices, Types of matrices, Operation on matrices, Transpose of a matrix, Matrix Multiplication, Determinants, Properties of determinants , Product of determinants, Minors and co-Factors, Adjoint or adjugate of a square matrix , Singular and non-singular matrices, Inverse of a matrix, Solution of system of linear of equations using matrix method, Cramer's rule, Characteristic equation and roots of a square matrix, Cayley–Hamilton theorem,Applicationof Matrices in solving Pharmacokinetic equations

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UNIT – III **06 Hours**

- **Calculus**

Differentiation : Introductions, Derivative of a function, Derivative of a constant, Derivative of a product of a constant and a function , Derivative of the sum or difference of two functions, Derivative of the product of two functions (product formula). Derivative of the quotient of two functions (Quotient formula) – **Without Proof,** Derivative of x^n *w.r.t*x,where n is any rational number, Derivative of e^x,, Derivative of $\log_e x$, Derivative of a^x,Derivative of trigonometric functions from first principles **(without Proof),** Successive Differentiation, Conditions for a function to be a maximum or a minimum at a point. Application

UNIT – IV **06 Hours**

- **Analytical Geometry**

Introduction: Signs of the Coordinates, Distance formula,
Straight Line : Slope or gradient of a straight line, Conditions for parallelism and perpendicularity of two lines, Slope of a line joining two points, Slope – intercept form of a straight line
Integration:
Introduction, Definition, Standard formulae, Rules of integration , Method of substitution, Method of Partial fractions, Integration by parts, definite integrals, application

UNIT-V **06 Hours**

- **Differential Equations** : Some basic definitions, Order and degree, Equations in separable form , Homogeneous equations, Linear Differential equations, Exact equations, **Application in solving Pharmacokinetic equations**
- **Laplace Transform** : Introduction, Definition, Properties of Laplace transform, Laplace Transforms of elementary functions, Inverse Laplace transforms, Laplace transform of derivatives, Application to solve Linear differential equations, **Application in solving Chemical kinetics and Pharmacokinetics equations**

Recommended Books (Latest Edition)

1. Differential Calculus by Shanthinarayan
2. Pharmaceutical Mathematics with application to Pharmacy by Panchaksharappa Gowda D.H.
3. Integral Calculus by Shanthinarayan
4. Higher Engineering Mathematics by Dr.B.S.Grewal

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Semester II

BP 201T. HUMAN ANATOMY AND PHYSIOLOGY-II (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives: Upon completion of this course the student should be able to:

1. Explain the gross morphology, structure and functions of various organs of the human body.
2. Describe the various homeostatic mechanisms and their imbalances.
3. Identify the various tissues and organs of different systems of human body.
4. Perform the hematological tests like blood cell counts, haemoglobin estimation, bleeding/clotting time etc and also record blood pressure, heart rate, pulse and respiratory volume.
5. Appreciate coordinated working pattern of different organs of each system
6. Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

Course Content:

Unit I **10 hours**

- **Nervous system**

Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, electrophysiology, action potential, nerve impulse, receptors, synapse, neurotransmitters.

Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid.structure and functions of brain (cerebrum, brain stem, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts,reflex activity)

Unit II **06 hours**

- **Digestive system**

Anatomy of GI Tract with special reference to anatomy and functions of stomach, (Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine

and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT.

- **Energetics**

  Formation and role of ATP, Creatinine Phosphate and BMR.

Unit III

- **Respiratory system** **10 hours**

  Anatomy of respiratory system with special reference to anatomy of lungs, mechanism of respiration, regulation of respiration.

  Lung Volumes and capacities transport of respiratory gases, artificial respiration, and resuscitation methods.

- **Urinary system**

  Anatomy of urinary tract with special reference to anatomy of kidney and nephrons, functions of kidney and urinary tract, physiology of urine formation, micturition reflex and role of kidneys in acid base balance, role of RAS in kidney and disorders of kidney.

Unit IV **10 hours**

- **Endocrine system**

  Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland, thymus and their disorders.

Unit V **09 hours**

- **Reproductive system**

  Anatomy of male and female reproductive system, Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition

- **Introduction to genetics**

  Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance

BP 207 P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject.

1. To study the integumentary and special senses using specimen, models, etc.,
2. To study the nervous system using specimen, models, etc.,
3. To study the endocrine system using specimen, models, etc
4. To demonstrate the general neurological examination
5. To demonstrate the function of olfactory nerve
6. To examine the different types of taste.
7. To demonstrate the visual acuity
8. To demonstrate the reflex activity
9. Recording of body temperature
10. To demonstrate positive and negative feedback mechanism.
11. Determination of tidal volume and vital capacity.
12. Study of digestive, respiratory, cardiovascular systems, urinary and reproductive systems with the help of models, charts and specimens.
13. Recording of basal mass index
14. Study of familyplanning devices and pregnancy diagnosis test.
15. Demonstration of total blood count by cell analyser
16. Permanent slides of vital organs and gonads.

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA

4. Text book of Medical Physiology- Arthur C,Guyton andJohn.E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brothers medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brothers medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books:

1. Physiological basis of Medical Practice-Best and Tailor: Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

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BP202T. PHARMACEUTICAL ORGANIC CHEMISTRY –I (Theory)

45 Hours

Scope: This subject deals with classification and nomenclature of simple organic compounds, structural isomerism, intermediates forming in reactions, important physical properties, reactions and methods of preparation of these compounds. The syllabus also emphasizes on mechanisms and orientation of reactions.

Objectives: Upon completion of the course the student shall be able to

1. write the structure, name and the type of isomerism of the organic compound
2. write the reaction, name the reaction and orientation of reactions
3. account for reactivity/stability of compounds,
4. identify/confirm the identification of organic compound

Course Content:

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT-I **07 Hours**

- **Classification, nomenclature and isomerism**

  Classification of Organic Compounds

  Common and IUPAC systems of nomenclature of organic compounds

  (up to 10 Carbons open chain and carbocyclic compounds)

Structural isomerisms in organic compounds

UNIT-II10 Hours

- **Alkanes*, Alkenes* and Conjugated dienes***

  SP^3 hybridization in alkanes, Halogenation of alkanes, uses of paraffins.

  Stabilities of alkenes, SP^2 hybridization in alkenes

  E_1 and E_2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E_1 verses E_2 reactions, Factors affecting E_1 and E_2 reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation.

  Stability of conjugated dienes, Diel-Alder, electrophilic addition, free radical addition reactions of conjugated dienes, allylic rearrangement

UNIT-III10 Hours

- **Alkyl halides***

  SN_1 and SN_2 reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations.

  SN_1 versus SN_2 reactions, Factors affecting SN_1 and SN_2 reactions

  Structure and uses of ethylchloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetrachloromethane and iodoform.

- **Alcohols***- Qualitative tests, Structure and uses of Ethyl alcohol, Methyl alcohol, chlorobutanol, Cetosteryl alcohol, Benzyl alcohol, Glycerol, Propylene glycol

UNIT-IV10 Hours

- **Carbonyl compounds* (Aldehydes and ketones)**

  Nucleophilic addition, Electromeric effect, aldol condensation, Crossed Aldol condensation, Cannizzaro reaction, Crossed Cannizzaro reaction, Benzoin condensation, Perkin condensation, qualitative tests, Structure and uses of Formaldehyde, Paraldehyde, Acetone, Chloral hydrate, Hexamine, Benzaldehyde, Vanilin, Cinnamaldehyde.

UNIT-V **08 Hours**

- **Carboxylic acids***

  Acidity of carboxylic acids, effect of substituents on acidity, inductive effect and qualitative tests for carboxylic acids ,amide and ester

  Structure and Uses of Acetic acid, Lactic acid, Tartaric acid, Citric acid, Succinic acid. Oxalic acid, Salicylic acid, Benzoic acid, Benzyl benzoate, Dimethyl phthalate, Methyl salicylate and Acetyl salicylic acid

- **Aliphatic amines*** - Basicity, effect of substituent on Basicity. Qualitative test, Structure and uses of Ethanolamine, Ethylenediamine, Amphetamine

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BP208P. PHARMACEUTICAL ORGANIC CHEMISTRY -I (Practical)

4 Hours / week

1. Systematic qualitative analysis of unknown organic compounds like
    1. Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation and unsaturation, etc.
    2. Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test
    3. Solubility test
    4. Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides.
    5. Melting point/Boiling point of organic compounds
    6. Identification of the unknown compound from the literature using melting point/ boiling point.
    7. Preparation of the derivatives and confirmation of the unknown compound by melting point/ boiling point.
    8. Minimum 5 unknown organic compounds to be analysed systematically.
2. Preparation of suitable solid derivatives from organic compounds
3. Construction of molecular models

Recommended Books (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar , Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K.Vishnoi.
8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.
9. Reaction and reaction mechanism by Ahluwaliah/Chatwal.

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BP203 T. BIOCHEMISTRY (Theory)

45 Hours

Scope: Biochemistry deals with complete understanding of the molecular levels of the chemical process associated with living cells. The scope of the subject is providing biochemical facts and the principles to understand metabolism of nutrient molecules in physiological and pathological conditions. It is also emphasizing on genetic organization of mammalian genome and hetero & autocatalytic functions of DNA.

Objectives: Upon completion of course student shell able to

1. Understand the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.
2. Understand the metabolism of nutrient molecules in physiological and pathological conditions.
3. Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.

Course Content:

UNIT I **08 Hours**

- **Biomolecules**

  Introduction, classification, chemical nature and biological role of carbohydrate, lipids, nucleic acids, amino acids and proteins.

- **Bioenergetics**

  Concept of free energy, endergonic and exergonic reaction, Relationship between free energy, enthalpy and entropy; Redox potential.

  Energy rich compounds; classification; biological significances of ATP and cyclic AMP

UNIT II **10 Hours**

- **Carbohydrate metabolism**

  Glycolysis – Pathway, energetics and significance

  Citric acid cycle- Pathway, energetics and significance

  HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency

  Glycogen metabolism Pathways and glycogen storage diseases (GSD)

  Gluconeogenesis- Pathway and its significance

  Hormonal regulation of blood glucose level and Diabetes mellitus

- **Biological oxidation**

  Electron transport chain (ETC) and its mechanism.

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Oxidative phosphorylation & its mechanism and substrate level phosphorylation

Inhibitors ETC and oxidative phosphorylation/Uncouplers

UNIT III **10 Hours**

- **Lipid metabolism**

  β-Oxidation of saturated fatty acid (Palmitic acid)

Formation and utilization of ketone bodies; ketoacidosis

De novo synthesis of fatty acids (Palmitic acid)

Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D

Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity.

- **Amino acid metabolism**

  General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders

  Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenyketonuria, Albinism, alkeptonuria, tyrosinemia)

  Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline

  Catabolism of heme; hyperbilirubinemia and jaundice

UNIT IV **10 Hours**

- **Nucleic acid metabolism and genetic information transfer**

  Biosynthesis of purine and pyrimidine nucleotides

  Catabolism of purine nucleotides and Hyperuricemia and Gout disease

  Organization of mammalian genome

  Structure of DNA and RNA and their functions

  DNA replication (semi conservative model)

  Transcription or RNA synthesis

  Genetic code, Translation or Protein synthesis and inhibitors

UNIT V **07 Hours**

- **Enzymes**

  Introduction, properties, nomenclature and IUB classification of enzymes

  Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)

  Enzyme inhibitors with examples

  Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation

  Therapeutic and diagnostic applications of enzymes and isoenzymes

  Coenzymes –Structure and biochemical functions

BP 209 P. BIOCHEMISTRY (Practical)

4 Hours / Week

1. Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and starch)
2. Identification tests for Proteins (albumin and Casein)
3. Quantitative analysis of reducing sugars (DNSA method) and Proteins (Biuret method)
4. Qualitative analysis of urine for abnormal constituents
5. Determination of blood creatinine
6. Determination of blood sugar
7. Determination of serum total cholesterol
8. Preparation of buffer solution and measurement of pH
9. Study of enzymatic hydrolysis of starch
10. Determination of Salivary amylase activity
11. Study the effect of Temperature on Salivary amylase activity.
12. Study the effect of substrate concentration on salivary amylase activity.

Recommended Books (Latest Editions)

1. Principles of Biochemistry by Lehninger.
2. Harper's Biochemistry by Robert K. Murry, Daryl K. Granner and Victor W. Rodwell.
3. Biochemistry by Stryer.
4. Biochemistry by D. Satyanarayan and U.Chakrapani
5. Textbook of Biochemistry by Rama Rao.
6. Textbook of Biochemistry by Deb.
7. Outlines of Biochemistry by Conn and Stumpf
8. Practical Biochemistry by R.C. Gupta and S. Bhargavan.
9. Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition)
10. Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.
11. Practical Biochemistry by Harold Varley.

BP 204T.PATHOPHYSIOLOGY (THEORY)

45Hours

Scope: Pathophysiology is the study of causes of diseases and reactions of the body to such disease producing causes.This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge required to practice medicine safely, confidently, rationally and effectively.

Objectives: Upon completion of the subject student shall be able to –

1. Describe the etiology and pathogenesis of the selected disease states;
2. Name the signs and symptoms of the diseases; and
3. Mention the complications of the diseases.

Course content:

Unit I **10Hours**

- **Basic principles of Cell injury and Adaptation:**
  Introduction, definitions, Homeostasis, Components and Types of Feedback systems, Causes of cellular injury,Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage),Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia),Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis &Alkalosis,Electrolyte imbalance

- **Basic mechanism involved in the process of inflammation and repair:** Introduction, Clinical signs of inflammation, Different types of Inflammation,Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of WBC's,Mediators of inflammation,Basic principles of wound healing in the skin,Pathophysiology of Atherosclerosis

Unit II **10Hours**

- **Cardiovascular System:** Hypertension, congestive heart failure, ischemic heart disease (angina,myocardial infarction, atherosclerosis and arteriosclerosis)
- **Respiratory system:**Asthma, Chronic obstructive airways diseases.
- **Renal system:**Acute and chronic renal failure .

Unit II **10Hours**

- **Haematological Diseases:** Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalasemia, hereditary acquired anemia, hemophilia
- **Endocrine system:** Diabetes, thyroid diseases, disorders of sex hormones
- **Nervous system:** Epilepsy, Parkinson's disease, stroke, psychiatric disorders: depression, schizophrenia and Alzheimer's disease.
- **Gastrointestinal system:** Peptic Ulcer
-

Unit IV **8 Hours**

- Inflammatory bowel diseases, jaundice, hepatitis (A,B,C,D,E,F) alcoholic liver disease.
- **Disease of bones and joints:** Rheumatoid arthritis, osteoporosis and gout
- **Principles of cancer:** classification, etiology and pathogenesis of cancer
- **Diseases of bones and joints:**Rheumatoid Arthritis, Osteoporosis,Gout

- **Principles of Cancer:** Classification, etiology and pathogenesis of Cancer

Unit V **7 Hours**

- **Infectious diseases:**Meningitis,Typhoid, Leprosy, Tuberculosis

Urinary tract infections

- **Sexually transmitted diseases:**AIDS, Syphilis, Gonorrhea

Recommended Books (Latest Editions)

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1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins &Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014.
2. Harsh Mohan; Text book of Pathology; 6th edition; India; Jaypee Publications; 2010.
3. Laurence B, Bruce C, Bjorn K. ; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12th edition; New York; McGraw-Hill; 2011.
4. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; united states;
5. William and Wilkins, Baltimore; 1991 [1990 printing].
6. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; Davidson's Principles and Practice of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.
7. Guyton A, John .E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders Company; 2010.
8. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw-Hill Medical; 2014.
9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997.
10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London; Churchill Livingstone publication; 2003.

Recommended Journals

1. The Journal of Pathology. ISSN: 1096-9896 (Online)
2. The American Journal of Pathology. ISSN: 0002-9440
3. Pathology. 1465-3931 (Online)
4. International Journal of Physiology, Pathophysiology and Pharmacology. ISSN: 1944-8171 (Online)
5. Indian Journal of Pathology and Microbiology. ISSN-0377-4929.

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BP205 T. COMPUTER APPLICATIONS IN PHARMACY (Theory)

30 Hrs (2 Hrs/Week)

Scope: This subject deals with the introduction Database, Database Management system, computer application in clinical studies and use of databases.

Objectives: Upon completion of the course the student shall be able to

1. know the various types of application of computers in pharmacy
2. know the various types of databases
3. know the various applications of databases in pharmacy

Course content:

UNIT – I **06 hours**

Number system: Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One's complement ,Two's complement method, binary multiplication, binary division

Concept of Information Systems and Software : Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project

UNIT –II **06 hours**

Web technologies:Introduction to HTML, XML,CSS and Programming languages, introduction to web servers and Server Products

Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database

UNIT – III **06 hours**

Application of computers in Pharmacy – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring

Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System

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UNIT – IV **06 hours**

Bioinformatics: Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery

UNIT-V **06 hours**

Computers as data analysis in Preclinical development:
Chromatographic dada analysis(CDS), Laboratory Information management System (LIMS) and Text Information Management System(TIMS)

BP210P. COMPUTER APPLICATIONS IN PHARMACY (Practical)

1. Design a questionnaire using a word processing package to gather information about a particular disease.
2. Create a HTML web page to show personal information.
3. Retrieve the information of a drug and its adverse effects using online tools
4. Creating mailing labels Using Label Wizard , generating label in MS WORD
5. Create a database in MS Access to store the patient information with the required fields Using access,
6. Design a form in MS Access to view, add, delete and modify the patient record in the database
7. Generating report and printing the report from patient database
8. Creating invoice table using – MS Access
9. Drug information storage and retrieval using MS Access
10. Creating and working with queries in MS Access
11. Exporting Tables, Queries, Forms and Reports to web pages
12. Exporting Tables, Queries, Forms and Reports to XML pages

Recommended books (Latest edition):

1. Computer Application in Pharmacy – William E.Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development –Sean Ekins – Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
3. Bioinformatics (Concept, Skills and Applications) – S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)
4. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N.Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi - 110002

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BP 206 T. ENVIRONMENTAL SCIENCES (Theory)

30 hours

Scope: Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment.

Objectives: Upon completion of the course the student shall be able to:

1. Create the awareness about environmental problems among learners.
2. Impart basic knowledge about the environment and its allied problems.
3. Develop an attitude of concern for the environment.
4. Motivate learner to participate in environment protection and environment improvement.
5. Acquire skills to help the concerned individuals in identifying and solving environmental problems.
6. Strive to attain harmony with Nature.

Course content:

Unit-I **10hours**

The Multidisciplinary nature of environmental studies

Natural Resources

Renewable and non-renewable resources:

Natural resources and associated problems

a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources.

Unit-II **10hours**

Ecosystems

- Concept of an ecosystem.
- Structure and function of an ecosystem.
- Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

Unit- III **10hours**

Environmental Pollution: Air pollution; Water pollution; Soil pollution

Recommended Books (Latest edition):

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
3. Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
5. Clark R.S., Marine Pollution, Clanderson Press Oxford
6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
7. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
8. Down of Earth, Centre for Science and Environment

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SEMESTER III

BP301T. PHARMACEUTICAL ORGANIC CHEMISTRY –II (Theory)

45 Hours

Scope: This subject deals with general methods of preparation and reactions of some organic compounds. Reactivity of organic compounds are also studied here. The syllabus emphasizes on mechanisms and orientation of reactions. Chemistry of fats and oils are also included in the syllabus.

Objectives: Upon completion of the course the student shall be able to

1. write the structure, name and the type of isomerism of the organic compound
2. write the reaction, name the reaction and orientation of reactions
3. account for reactivity/stability of compounds,
4. prepare organic compounds

Course Content:

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT I **10 Hours**

- **Benzene and its derivatives**
  - **A.** Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule
  - **B.** Reactions of benzene - nitration, sulphonation, halogenation-reactivity, Friedelcrafts alkylation- reactivity, limitations, Friedelcrafts acylation.
  - **C.** Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction
  - **D.** Structure and uses of DDT, Saccharin, BHC and Chloramine

UNIT II **10 Hours**

- **Phenols*** - Acidity of phenols, effect of substituents on acidity, qualitative tests, Structure and uses of phenol, cresols, resorcinol, naphthols
- **Aromatic Amines*** - Basicity of amines, effect of substituents on basicity, and synthetic uses of aryl diazonium salts
- **Aromatic Acids*** –Acidity, effect of substituents on acidity and important reactions of benzoic acid.

UNIT III

10 Hours

- **Fats and Oils**

a. Fatty acids – reactions.

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b. Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.

c. Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination.

UNIT IV **08 Hours**

- **Polynuclear hydrocarbons:**

a. Synthesis, reactions

b. Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives

UNIT V **07 Hours**

- **Cyclo alkanes***

Stabilities – Baeyer's strain theory, limitation of Baeyer's strain theory, Coulson and Moffitt's modification, Sachse Mohr's theory (Theory of strainless rings), reactions of cyclopropane and cyclobutane only

BP305P. PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)

4 Hrs/week

I Experiments involving laboratory techniques

- Recrystallization
- Steam distillation

II Determination of following oil values (including standardization of reagents)

- Acid value
- Saponification value
- Iodine value

III Preparation of compounds

- Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction.
- 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/
- Acetanilide by halogenation (Bromination) reaction.
- 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction.
- Benzoic acid from Benzyl chloride by oxidation reaction.
- Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
- 1-Phenyl azo-2-napthol from Aniline by diazotization and coupling reactions.
- Benzil from Benzoin by oxidation reaction.
- Dibenzal acetone from Benzaldehyde by Claison Schmidt reaction
- Cinnammic acid from Benzaldehyde by Perkin reaction
- *P*-Iodo benzoic acid from *P*-amino benzoic acid

Recommended Books (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar , Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K.Vishnoi.

8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.

BP302T. PHYSICAL PHARMACEUTICS-I (Theory)

45Hours

Scope: The course deals with the various physica and physicochemical properties, and principles involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

Objectives: Upon the completion of the course student shall be able to

1. Understand various physicochemical properties of drug molecules in the designing the dosage forms
2. Know the principles of chemical kinetics & to use them for stability testing nad determination of expiry date of formulations
3. Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

Course Content:

UNIT-I **10 Hours**

Solubility of drugs: Solubility expressions, mechanisms of solute solvent interactions, ideal solubility parameters, solvation & association, quantitative approach to the factors influencing solubility of drugs, diffusion principles in biological systems. Solubility of gas in liquids, solubility of liquids in liquids, (Binary solutions, ideal solutions) Raoult's law, real solutions. Partially miscible liquids, Critical solution temperature and applications. Distribution law, its limitations and applications

UNIT-II **10Hours**

States of Matter and properties of matter: State of matter, changes in the state of matter, latent heats, vapour pressure, sublimation critical point, eutectic mixtures, gases, aerosols – inhalers, relative humidity, liquid complexes, liquid crystals, glassy states, solid-crystalline, amorphous & polymorphism.

Physicochemical properties of drug molecules: Refractive index, optical rotation, dielectric constant, dipole moment, dissociation constant, determinations and applications

UNIT-III **08 Hours**

Surface and interfacial phenomenon: Liquid interface, surface & interfacial tensions,

surface free energy, measurement of surface & interfacial tensions, spreading coefficient, adsorption at liquid interfaces, surface active agents, HLB Scale, solubilisation, detergency, adsorption at solid interface.

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UNIT-IV **08Hours**

Complexation and protein binding: Introduction, Classification of Complexation, Applications, methods of analysis, protein binding, Complexation and drug action, crystalline structures of complexes and thermodynamic treatment of stability constants.

UNIT-V **07 Hours**

pH, buffers and Isotonic solutions: Sorensen's pH scale, pH determination (electrometric and calorimetric), applications of buffers, buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, buffered isotonic solutions.

BP306P. PHYSICAL PHARMACEUTICS – I (Practical)

4 Hrs/week

1. Determination the solubility of drug at room temperature
2. Determination of pKa value by Half Neutralization/ Henderson Hasselbalch equation.
3. Determination of Partition co- efficient of benzoic acid in benzene and water
4. Determination of Partition co- efficient of Iodine in CCl_4 and water
5. Determination of % composition of NaCl in a solution using phenol-water system by CST method
6. Determination of surface tension of given liquids by drop count and drop weight method
7. Determination of HLB number of a surfactant by saponification method
8. Determination of Freundlich and Langmuir constants using activated char coal
9. Determination of critical micellar concentration of surfactants
10. Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubility method
11. Determination of stability constant and donor acceptor ratio of Cupric-Glycine complex by pH titration method

Recommended Books: (Latest Editions)

1. Physical Pharmacy by Alfred Martin
2. Experimental Pharmaceutics by Eugene, Parott.
3. Tutorial Pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical Calculations, Lea &Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, MarcelDekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical Dosage-forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C and ManavalanR.
8. Laboratory Manual of Physical Pharmaceutics, C.V.S. Subramanyam, J. Thimma settee
9. Physical Pharmaceutics by C.V.S. Subramanyam
10. Test book of Physical Phramacy, by Gaurav Jain & Roop K. Khar

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BP 303 T. PHARMACEUTICAL MICROBIOLOGY (Theory)

45Hours

Scope:

- Study of all categories of microorganisims especially for the production of alchol antibiotics, vaccines, vitamins enzymes etc..

Objectives: Upon completion of the subject student shall be able to;

1. Understand methods of identification, cultivation and preservation of various microorganisms
2. To understand the importance and implementation of sterlization in pharmaceutical processing and industry
3. Learn sterility testing of pharmaceutical products.
4. Carried out microbiological standardization of Pharmaceuticals.
5. Understand the cell culture technology and its applications in pharmaceutical industries.

Course content:

Unit I **10 Hours**

Introduction, history of microbiology, its branches, scope and its importance.
Introduction to Prokaryotes and Eukaryotes
Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count).
Study of different types of phase constrast microscopy, dark field microscopy and electron microscopy.

Unit II **10 Hours**

Identification of bacteria using staining techniques (simple, Gram's &Acid fast staining) and biochemical tests (IMViC).

Study of principle, procedure, merits, demerits and applications of physical, chemical gaseous,radiation and mechanical method of sterilization.

Evaluation of the efficiency of sterilization methods.

Equipments employed in large scale sterilization.

Sterility indicators.

Unit III **10 Hours**

Study of morphology, classification, reproduction/replication and cultivation of Fungi and Viruses.

Classification and mode of action of disinfectants

Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions

Evaluation of bactericidal & Bacteriostatic.

Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP.

Unit IV **08 Hours**

Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification.
Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids.
Assessment of a new antibiotic.

Unit V **07Hours**

Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage.

Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations.

Growth of animal cells in culture, general procedure for cell culture, Primary, established and transformed cell cultures.

Application of cell cultures in pharmaceutical industry and research.

BP 307P.PHARMACEUTICAL MICROBIOLOGY (Practical)

4 Hrs/week

1. Introduction and study of different equipments and processing, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, microscopes used in experimental microbiology.
2. Sterilization of glassware, preparation and sterilization of media.
3. Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations.
4. Staining methods- Simple, Grams staining and acid fast staining (Demonstration with practical).
5. Isolation of pure culture of micro-organisms by multiple streak plate technique and other techniques.
6. Microbiological assay of antibiotics by cup plate method and other methods
7. Motility determination by Hanging drop method.
8. Sterility testing of pharmaceuticals.
9. Bacteriological analysis of water
10. Biochemical test.

Recommended Books (Latest edition)

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. I.P., B.P., U.S.P.- latest editions.
10. Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai
11. Edward: Fundamentals of Microbiology.
12. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company

BP 304 T. PHARMACEUTICAL ENGINEERING (Theory)

45 Hours

Scope: This course is designed to impart a fundamental knowledge on the art and science of various unit operations used in pharmaceutical industry.

Objectives: Upon completion of the course student shall be able:

1. To know various unit operations used in Pharmaceutical industries.
2. To understand the material handling techniques.
3. To perform various processes involved in pharmaceutical manufacturing process.
4. To carry out various test to prevent environmental pollution.
5. To appreciate and comprehend significance of plant lay out design for optimum use of resources.
6. To appreciate the various preventive methods used for corrosion control in Pharmaceutical industries.

Course content:

UNIT-I **10 Hours**

- **Flow of fluids:** Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Energy losses, Orifice meter, Venturimeter, Pitot tube and Rotometer.
- **Size Reduction:** Objectives, Mechanisms & Laws governing size reduction, factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & end runner mill.
- **Size Separation:** Objectives, applications & mechanism of size separation, official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter & elutriation tank.

UNIT-II **10 Hours**

- **Heat Transfer:** Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers.

- **Evaporation:** Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator& Economy of multiple effect evaporator.

- **Distillation:** Basic Principles and methodology of simple distillation,flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

UNIT- III **08 Hours**

- **Drying:** Objectives, applications & mechanism of drying process, measurements & applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer.

- **Mixing:** Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles & Silverson Emulsifier,

UNIT-IV **08 Hours**

- **Filtration:** Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filters and Seidtz filter.
- **Centrifugation:** Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge, semi continuous centrifuge & super centrifuge.

UNIT- V **07 Hours**

- **Materials of pharmaceutical plant construction, Corrosion and its prevention:** Factors affecting during materials selected for Pharmaceutical plant construction, Theories of corrosion, types of corrosion and there prevention. Ferrous and nonferrous metals, inorganic and organic non metals, basic of material handling systems.

Recommended Books: (Latest Editions)

1. Introduction to chemical engineering – Walter L Badger & Julius Banchero, Latest edition.
2. Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson- Latest edition.
3. Unit operation of chemical engineering – Mcabe Smith, Latest edition.
4. Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest edition.
5. Remington practice of pharmacy- Martin, Latest edition.
6. Theory and practice of industrial pharmacy by Lachmann., Latest edition.
7. Physical pharmaceutics- C.V.S Subrahmanyam et al., Latest edition.
8. Cooper and Gunn's Tutorial pharmacy, S.J. Carter, Latest edition.

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BP308P - PHARMACEUTICAL ENGINEERING (Practical)

4 Hours/week

I. Determination of radiation constant of brass, iron, unpainted and painted glass.
II. Steam distillation – To calculate the efficiency of steam distillation.
III. To determine the overall heat transfer coefficient by heat exchanger.
IV. Construction of drying curves (for calcium carbonate and starch).
V. Determination of moisture content and loss on drying.
VI. Determination of humidity of air – i) From wet and dry bulb temperatures –use of Dew point method.
VII. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.
VIII. Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic andlogarithmic probability plots.
IX. Size reduction: To verify the laws of size reduction using ball mill and determining Kicks, Rittinger's, Bond's coefficients, power requirement and critical speed of Ball Mill.
X. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such othermajor equipment.
XI. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity
XII. To study the effect of time on the Rate of Crystallization.
XIII. To calculate the uniformity Index for given sample by using Double Cone Blender.

SEMESTER IV

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BP401T. PHARMACEUTICAL ORGANIC CHEMISTRY –III (Theory)

45 Hours

Scope: This subject imparts knowledge on stereo-chemical aspects of organic compounds and organic reactions, important named reactions, chemistry of important hetero cyclic compounds. It also emphasizes on medicinal and other uses of organic compounds.

Objectives: At the end of the course, the student shall be able to

1. understand the methods of preparation and properties of organic compounds
2. explain the stereo chemical aspects of organic compounds and stereo chemical reactions
3. know the medicinal uses and other applications of organic compounds

Course Content:

Note: To emphasize on definition, types, mechanisms, examples, uses/applications

UNIT-I **10 Hours**

Stereo isomerism

Optical isomerism –

Optical activity, enantiomerism, diastereoisomerism, meso compounds

Elements of symmetry, chiral and achiral molecules

DL system of nomenclature of optical isomers, sequence rules, RS system of nomenclature of optical isomers

Reactions of chiral molecules

Racemic modification and resolution of racemic mixture.

Asymmetric synthesis: partial and absolute

UNIT-II **10 Hours**

Geometrical isomerism

Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Anti systems)

Methods of determination of configuration of geometrical isomers.

Conformational isomerism in Ethane, n-Butane and Cyclohexane.

Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity.

Stereospecific and stereoselective reactions

UNIT-III **10 Hours**

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Heterocyclic compounds:

Nomenclature and classification

Synthesis, reactions and medicinal uses of following compounds/derivatives

Pyrrole, Furan, and Thiophene

Relative aromaticity and reactivity of Pyrrole, Furan and Thiophene

UNIT-IV **8 Hours**

Synthesis, reactions and medicinal uses of following compounds/derivatives

Pyrazole, Imidazole, Oxazole and Thiazole.

Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicity of pyridine

Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives

UNIT-V **07 Hours**

Reactions of synthetic importance

Metal hydride reduction ($NaBH_4$ and $LiAlH_4$), Clemmensen reduction, Birch reduction, Wolff Kishner reduction.

Oppenauer-oxidation and Dakin reaction.

Beckmanns rearrangement and Schmidt rearrangement.

Claisen-Schmidt condensation

Recommended Books (Latest Editions)

1. Organic chemistry by I.L. Finar, Volume-I & II.
2. A text book of organic chemistry – Arun Bahl, B.S. Bahl.
3. Heterocyclic Chemistry by Raj K. Bansal
4. Organic Chemistry by Morrison and Boyd
5. Heterocyclic Chemistry by T.L. Gilchrist

BP402T. MEDICINAL CHEMISTRY – I (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

Objectives: Upon completion of the course the student shall be able to

1. understand the chemistry of drugs with respect to their pharmacological activity
2. understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. know the Structural Activity Relationship (SAR) of different class of drugs
4. write the chemical synthesis of some drugs

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

UNIT- I **10 Hours**

Introduction to Medicinal Chemistry

History and development of medicinal chemistry

Physicochemical properties in relation to biological action

Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Protein binding, Chelation, Bioisosterism, Optical and Geometrical isomerism.

Drug metabolism

Drug metabolism principles- Phase I and Phase II.

Factors affecting drug metabolism including stereo chemical aspects.

UNIT- II **10 Hours**

Drugs acting on Autonomic Nervous System

Adrenergic Neurotransmitters:

Biosynthesis and catabolism of catecholamine.

Adrenergic receptors (Alpha & Beta) and their distribution.

Sympathomimetic agents: SAR of Sympathomimetic agents

Direct acting: Nor-epinephrine, Epinephrine, Phenylephrine*, Dopamine,

Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline.

- Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine.
- Agents with mixed mechanism: Ephedrine, Metaraminol.

Adrenergic Antagonists:

Alpha adrenergic blockers: Tolazoline*, Phentolamine. Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide.

Beta adrenergic blockers: SAR of beta blockers, Propranolol*, Metibranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol.

UNIT-III **10 Hours**

Cholinergic neurotransmitters:

Biosynthesis and catabolism of acetylcholine.

Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

Parasympathomimetic agents: SAR of Parasympathomimetic agents

Direct acting agents: Acetylcholine, Carbachol*, Bethanechol, Methacholine, Pilocarpine.

Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible): Physostigmine, Neostigmine*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorphate, Echothiophate iodide, Parathione, Malathion.

Cholinesterase reactivator: Pralidoxime chloride.

Cholinergic Blocking agents: SAR of cholinolytic agents

Solanaceous alkaloids and analogues: Atropine sulphate, Hyoscyamine sulphate, Scopolamine hydrobromide, Homatropine hydrobromide, Ipratropium bromide*.

Synthetic cholinergic blocking agents: Tropicamide, Cyclopentolate hydrochloride, Clidinium bromide, Dicyclomine hydrochloride*, Glycopyrrolate, Methantheline bromide, Propantheline bromide, Benztropine mesylate, Orphenadrine citrate, Biperidine hydrochloride, Procyclidine hydrochloride*, Tridihexethyl chloride, Isopropamide iodide, Ethopropazine hydrochloride.

UNIT- IV **08 Hours**

Drugs acting on Central Nervous System

A. Sedatives and Hypnotics:

Benzodiazepines: SAR of Benzodiazepines, Chlordiazepoxide, Diazepam*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem

Barbiturtes: SAR of barbiturates, Barbital*, Phenobarbital, Mephobarbital, Amobarbital, Butabarbital, Pentobarbital, Secobarbital

Miscelleneous:

Amides & imides: Glutethmide.

Alcohol & their carbamate derivatives: Meprobomate, Ethchlorvynol.

Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

B. Antipsychotics

Phenothiazeines: SAR of Phenothiazeines - Promazine hydrochloride, Chlorpromazine hydrochloride*, Triflupromazine, Thioridazine hydrochloride, Piperacetazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hydrochloride.

Ring Analogues of Phenothiazeines: Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine.

Fluro buterophenones: Haloperidol, Droperidol, Risperidone.

Beta amino ketones: Molindone hydrochloride.

Benzamides: Sulpieride.

C. Anticonvulsants: SAR of Anticonvulsants, mechanism of anticonvulsant action

Barbiturates: Phenobarbitone, Methabarbital. **Hydantoins:**

Phenytoin*, Mephenytoin, Ethotoin **Oxazolidine diones:**

Trimethadione, Paramethadione **Succinimides:**

Phensuximide, Methsuximide, Ethosuximide* **Urea and**

monoacylureas: Phenacemide, Carbamazepine*

Benzodiazepines: Clonazepam

Miscellaneous: Primidone, Valproic acid , Gabapentin, Felbamate

UNIT – V **07 Hours**

Drugs acting on Central Nervous System

General anesthetics:

Inhalation anesthetics: Halothane*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane.

Ultra short acting barbitutrates: Methohexital sodium*, Thiamylal sodium, Thiopental sodium.

Dissociative anesthetics: Ketamine hydrochloride.*

Narcotic and non-narcotic analgesics

Morphine and related drugs: SAR of Morphine analogues, Morphine sulphate, Codeine, Meperidine hydrochloride, Anilerdine hydrochloride, Diphenoxylate hydrochloride, Loperamide hydrochloride, Fentanyl citrate*, Methadone hydrochloride*, Propoxyphene hydrochloride, Pentazocine, Levorphanol tartarate.

Narcotic antagonists: Nalorphine hydrochloride, Levallorphan tartarate, Naloxone hydrochloride.

Anti-inflammatory agents: Sodium salicylate, Aspirin, Mefenamic acid*, Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepriac, Diclofenac, Ketorolac, Ibuprofen*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone.

BP406P. MEDICINAL CHEMISTRY – I (Practical)

4 Hours/Week

I	**Preparation of drugs/ intermediates**
1	1,3-pyrazole
2	1,3-oxazole
3	Benzimidazole
4	Benztriazole
5	2,3- diphenyl quinoxaline
6	Benzocaine
7	Phenytoin
8	Phenothiazine
9	Barbiturate
II	**Assay of drugs**
1	Chlorpromazine
2	Phenobarbitone
3	Atropine
4	Ibuprofen
5	Aspirin
6	Furosemide
III	**Determination of Partition coefficient for any two drugs**

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.

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7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

BP 403 T. PHYSICAL PHARMACEUTICS-II (Theory)

45Hours

Scope: The course deals with the various physica and physicochemical properties, and principles involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

Objectives: Upon the completion of the course student shall be able to

1. Understand various physicochemical properties of drug molecules in the designing the dosage forms
2. Know the principles of chemical kinetics & to use them for stability testing nad determination of expiry date offormulations
3. Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

Course Content:

UNIT-I **07 Hours**

Colloidal dispersions: Classification of dispersed systems & their general characteristics, size & shapes of colloidal particles, classification of colloids & comparative account of their general properties. Optical, kinetic & electrical properties. Effect of electrolytes, coacervation, peptization& protective action.

UNIT-II **10 Hours**

Rheology: Newtonian systems, law of flow, kinematic viscosity, effect of temperature, non-Newtonian systems, pseudoplastic, dilatant, plastic, thixotropy, thixotropy in formulation, determination of viscosity, capillary, falling Sphere, rotational viscometers

Deformation of solids: Plastic and elastic deformation, Heckel equation, Stress, Strain, Elastic Modulus

UNIT-III **10 Hours**

Coarse dispersion: Suspension, interfacial properties of suspended particles, settling in suspensions, formulation of flocculated and deflocculated suspensions. Emulsions and theories of emulsification, microemulsion and multiple emulsions; Stability of emulsions, preservation of emulsions, rheological properties of emulsions and emulsion formulation by HLB method.

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UNIT-IV **10Hours**

Micromeretics: Particle size and distribution, mean particle size, number and weight distribution, particle number, methods for determining particle size by different methods, counting and separation method, particle shape, specific surface, methods for determining surface area, permeability, adsorption, derived properties of powders, porosity, packing arrangement, densities, bulkiness & flow properties.

UNIT-V **10 Hours**

Drug stability: Reaction kinetics: zero, pseudo-zero, first & second order, units of basic rate constants, determination of reaction order. Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength, dielectric constant, specific & general acid base catalysis, Simple numerical problems. Stabilization of medicinal agents against common reactions like hydrolysis & oxidation. Accelerated stability testing in expiration dating of pharmaceutical dosage forms. Photolytic degradation and its prevention

BP 407P. PHYSICAL PHARMACEUTICS- II (Practical)

3 Hrs/week

1. Determination of particle size, particle size distribution using sieving method
2. Determination of particle size, particle size distribution using Microscopic method
3. Determination of bulk density, true density and porosity
4. Determine the angle of repose and influence of lubricant on angle of repose
5. Determination of viscosity of liquid using Ostwald's viscometer
6. Determination sedimentation volume with effect of different suspending agent
7. Determination sedimentation volume with effect of different concentration of single suspending agent
8. Determination of viscosity of semisolid by using Brookfield viscometer
9. Determination of reaction rate constant first order.
10. Determination of reaction rate constant second order
11. Accelerated stability studies

Recommended Books: (Latest Editions)

1. Physical Pharmacy by Alfred Martin, Sixth edition
2. Experimental pharmaceutics by Eugene, Parott.
3. Tutorial pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical calculations, Lea & Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, Marcel Dekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C, and Manavalan R.

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BP 404 T. PHARMACOLOGY-I (Theory)

45 Hrs

Scope: The main purpose of the subject is to understand what drugs do to the living organisms and how their effects can be applied to therapeutics. The subject covers the information about the drugs like, mechanism of action, physiological and biochemical effects (pharmacodynamics) as well as absorption, distribution, metabolism and excretion (pharmacokinetics) along with the adverse effects, clinical uses, interactions, doses, contraindications and routes of administration of different classes of drugs.

Objectives: Upon completion of this course the student should be able to

1. Understand the pharmacological actions of different categories of drugs
2. Explain the mechanism of drug action at organ system/sub cellular/ macromolecular levels.
3. Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.
4. Observe the effect of drugs on animals by simulated experiments
5. Appreciate correlation of pharmacology with other bio medical sciences

Course Content:

UNIT-I **08 hours**

1. General Pharmacology

a. Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, antagonists(competitive and non competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.

b. Pharmacokinetics- Membrane transport, absorption, distribution, mētābolism and excretion of drugs .Enzyme induction, enzyme inhibition, kinetics of elimination

UNIT-II **12 Hours**

General Pharmacology

a. Pharmacodynamics- Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors. drug receptors interactions signal transduction mechanisms, G-protein–coupled receptors, ion channel receptor, transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action.
b. Adverse drug reactions.
c. Drug interactions (pharmacokinetic and pharmacodynamic)
d. Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.

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UNIT-III **10 Hours**

2. Pharmacology of drugs acting on peripheral nervous system

a. Organization and function of ANS.

b.Neurohumoral transmission,co-transmission and classification of neurotransmitters.

c. Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics.

d. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).

e. Local anesthetic agents.

f. Drugs used in myasthenia gravis and glaucoma

UNIT-IV **08 Hours**

3. Pharmacology of drugs acting on central nervous system

a. Neurohumoral transmission in the C.N.S.special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine.

b. General anesthetics and pre-anesthetics.

c. Sedatives, hypnotics and centrally acting muscle relaxants.

d. Anti-epileptics

e. Alcohols and disulfiram

UNIT-V **07 Hours**

3. Pharmacology of drugs acting on central nervous system

a. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens.

b. Drugs used in Parkinsons disease and Alzheimer's disease.

c. CNS stimulants and nootropics.

d. Opioid analgesics and antagonists

e. Drug addiction, drug abuse, tolerance and dependence.

BP 408 P.PHARMACOLOGY-I (Practical)

4Hrs/Week

1. Introduction to experimental pharmacology.
2. Commonly used instruments in experimental pharmacology.
3. Study of common laboratory animals.
4. Maintenance of laboratory animals as per CPCSEA guidelines.
5. Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.
6. Study of different routes of drugs administration in mice/rats.
7. Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping time in mice.
8. Effect of drugs on ciliary motility of frog oesophagus
9. Effect of drugs on rabbit eye.
10. Effects of skeletal muscle relaxants using rota-rod apparatus.
11. Effect of drugs on locomotor activity using actophotometer.
12. Anticonvulsant effect of drugs by MES and PTZ method.
13. Study of stereotype and anti-catatonic activity of drugs on rats/mice.
14. Study of anxiolytic activity of drugs using rats/mice.
15. Study of local anesthetics by different methods

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology,.Churchil Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology

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6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.

7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher

8. Modern Pharmacology with clinical Applications, by Charles R.Craig&Robert,

9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.

10. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,

BP 405 T.PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory)

45 Hours

Scope: The subject involves the fundamentals of Pharmacognosy like scope, classification of crude drugs, their identification and evaluation, phytochemicals present in them and their medicinal properties.

Objectives: Upon completion of the course, the student shall be able

1. to know the techniques in the cultivation and production of crude drugs
2. to know the crude drugs, their uses and chemical nature
3. know the evaluation techniques for the herbal drugs
4. to carry out the microscopic and morphological evaluation of crude drugs

Course Content:

UNIT-I **10 Hours**

Introduction to Pharmacognosy:

(a) Definition, history, scope and development of Pharmacognosy

(b) Sources of Drugs – Plants, Animals, Marine & Tissue culture

(c) Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo- gum -resins).

Classification of drugs:

Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and sero taxonomical classification of drugs

Quality control of Drugs of Natural Origin:

Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical, chemical and biological methods and properties.

Quantitative microscopy of crude drugs including lycopodium spore method, leafconstants, camera lucida and diagrams of microscopic objects to scale with camera lucida.

UNIT-II **10 Hours**

Cultivation, Collection, Processing and storage of drugs of natural origin:

Cultivation and Collection of drugs of natural origin

Factors influencing cultivation of medicinal plants.

Plant hormones and their applications.

Polyploidy, mutation and hybridization with reference to medicinal plants

Conservation of medicinal plants

UNIT-III **07 Hours**

Plant tissue culture:

Historical development of plant tissue culture, types of cultures, Nutritional requirements, growth and their maintenance.

Applications of plant tissue culture in pharmacognosy.

Edible vaccines

UNIT IV **10 Hours**

Pharmacognosy in various systems of medicine:

Role of Pharmacognosy in allopathy and traditional systems of medicine namely, Ayurveda, Unani, Siddha, Homeopathy and Chinese systems of medicine.

Introduction to secondary metabolites:

Definition, classification, properties and test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins

UNIT V **08 Hours**

Study of biological source, chemical nature and uses of drugs of natural origin containing following drugs

Plant Products:

Fibers - Cotton, Jute, Hemp

Hallucinogens, Teratogens, Natural allergens

Primary metabolites:

General introduction, detailed study with respect to chemistry, sources, preparation, evaluation, preservation, storage, therapeutic used and commercial utility as Pharmaceutical Aids and/or Medicines for the following Primary metabolites:

Carbohydrates: Acacia, Agar, Tragacanth, Honey

Proteins and Enzymes : Gelatin, casein, proteolytic enzymes (Papain, bromelain, serratiopeptidase, urokinase, streptokinase, pepsin).

Lipids(Waxes, fats, fixed oils) : Castor oil, Chaulmoogra oil, Wool Fat, Bees Wax

Marine Drugs:

Novel medicinal agents from marine sources

BP408 P. PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical)

4 Hours/Week

1. Analysis of crude drugs by chemical tests: (i)Tragaccanth (ii) Acacia (iii)Agar (iv) Gelatin (v) starch (vi) Honey (vii) Castor oil
2. Determination of stomatal number and index
3. Determination of vein islet number, vein islet termination and paliside ratio.
4. Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer
5. Determination of Fiber length and width
6. Determination of number of starch grains by Lycopodium spore method
7. Determination of Ash value
8. Determination of Extractive values of crude drugs
9. Determination of moisture content of crude drugs
10. Determination of swelling index and foaming

Recommended Books: (Latest Editions)

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
2. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, 1988.
3. Text Book of Pharmacognosy by T.E. Wallis
4. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
5. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
6. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
7. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae
9. Anatomy of Crude Drugs by M.A. Iyengar

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SEMESTER V

BP501T. MEDICINAL CHEMISTRY – II (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

Objectives: Upon completion of the course the student shall be able to

1. Understand the chemistry of drugs with respect to their pharmacological activity
2. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. Know the Structural Activity Relationship of different class of drugs
4. Study the chemical synthesis of selected drugs

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

UNIT- I **10 Hours**

Antihistaminic agents: Histamine, receptors and their distribution in the humanbody

H_1–antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines succinate, Clemastine fumarate, Diphenylphyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium

H_2-antagonists: Cimetidine*, Famotidine, Ranitidin.

Gastric Proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole

Anti-neoplastic agents:

Alkylating agents: Meclorethamine*, Cyclophosphamide, Melphalan,

Chlorambucil, Busulfan, Thiotepa

Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin

Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate

Miscellaneous: Cisplatin, Mitotane.

UNIT – II **10 Hours**

Anti-anginal:

Vasodilators: Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbide dinitrite*, Dipyridamole.

Calcium channel blockers: Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine.

Diuretics:

Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorphenamide.

Thiazides: Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide,

Loop diuretics: Furosemide*, Bumetanide, Ethacrynic acid.

Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.

Osmotic Diuretics: Mannitol

Anti-hypertensive Agents: Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.

UNIT- III **10 Hours**

Anti-arrhythmic Drugs: Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate*, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcainide hydrochloride, Amiodarone, Sotalol.

Anti-hyperlipidemic agents: Clofibrate, Lovastatin, Cholesteramine and Cholestipol

Coagulant & Anticoagulants: Menadione, Acetomenadione, Warfarin*, Anisindione, clopidogrel

Drugs used in Congestive Heart Failure: Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan.

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UNIT- IV **08 Hours**

Drugs acting on Endocrine system

Nomenclature, Stereochemistry and metabolism of steroids

Sex hormones: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol.
Drugs for erectile dysfunction: Sildenafil, Tadalafil.
Oral contraceptives: Mifepristone, Norgestril, Levonorgestrol
Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone
Thyroid and antithyroid drugs: L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.

UNIT – V **07 Hours**

Antidiabetic agents:

Insulin and its preparations

Sulfonyl ureas: Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride.

Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acrabose, Voglibose.

Local Anesthetics: SAR of Local anesthetics

Benzoic Acid derivatives; Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine.

Amino Benzoic acid derivatives: Benzocaine*, Butamben, Procaine*, Butacaine, Propoxycaine, Tetracaine, Benoxinate.

Lidocaine/Anilide derivatives: Lignocaine, Mepivacaine, Prilocaine, Etidocaine.

Miscellaneous: Phenacaine, Diperodon, Dibucaine.*

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1to 5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

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BP 502 T. Industrial Pharmacyl (Theory)

45 Hours

Scope: Course enables the student to understand and appreciate the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product.

Objectives: Upon completion of the course the student shall be able to

1. Know the various pharmaceutical dosage forms and their manufacturing techniques.
2. Know various considerations in development of pharmaceutical dosage forms
3. Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

Course content:

3 hours/ week

UNIT-I **07 Hours**

Preformulation Studies: Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances.

a. Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism

b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization

BCS classification of drugs & its significant

Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

UNIT-II **10 Hours**

Tablets:

a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.

b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.

c. Quality control tests: In process and finished product tests

Liquid orals: Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia

UNIT-III **08 Hours**

Capsules:

a. ***Hard gelatin capsules:*** Introduction, Production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.

b. ***Soft gelatin capsules:*** Nature of shell and capsule content, size of capsules,importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications.

Pellets: Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets

UNIT-IV **10 Hours**

Parenteral Products:

a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity

b. Production procedure, production facilities and controls, aseptic processing

c. Formulation of injections, sterile powders, large volume parenterals and lyophilized products.

d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests of parenteral products.

Ophthalmic Preparations: Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations

UNIT-V **10 Hours**

Cosmetics: Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens.

Pharmaceutical Aerosols: Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies.

Packaging Materials Science: Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.

BP 506 P. Industrial Pharmacyl (Practical)

4 Hours/week

1. Preformulation studies on paracetamol/asparin/or any other drug
2. Preparation and evaluation of Paracetamol tablets
3. Preparation and evaluation of Aspirin tablets
4. Coating of tablets- film coating of tables/granules
5. Preparation and evaluation of Tetracycline capsules
6. Preparation of Calcium Gluconate injection
7. Preparation of Ascorbic Acid injection
8. Qulaity control test of (as per IP) marketed tablets and capsules
9. Preparation of Eye drops/ and Eye ointments
10. Preparation of Creams (cold / vanishing cream)
11. Evaluation of Glass containers (as per IP)

Recommended Books: (Latest Editions)

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman &J.B.Schwartz
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman
3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman
4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition
5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS)
6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman
7. Pharmaceutics- The science of dosage form design by M.E.Aulton, Churchill livingstone, Latest edition
8. Introduction to Pharmaceutical Dosage Forms by H. C.Ansel, Lea &Febiger, Philadelphia, 5th edition, 2005
9. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.

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BP503.T. PHARMACOLOGY-II (Theory)

45 Hours

Scope: This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on different systems of body and in addition,emphasis on the basic concepts of bioassay.

Objectives: Upon completion of this course the student should be able to

1. Understand the mechanism of drug action and its relevance in the treatment of different diseases
2. Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments
3. Demonstrate the various receptor actions using isolated tissue preparation
4. Appreciate correlation of pharmacology with related medical sciences

Course Content:

UNIT-I **10hours**

1. Pharmacology of drugs acting on cardio vascular system

a. Introduction to hemodynamic and electrophysiology of heart.
b. Drugs used in congestive heart failure
c. Anti-hypertensive drugs.
d. Anti-anginal drugs.
e. Anti-arrhythmic drugs.
f. Anti-hyperlipidemic drugs.

UNIT-II **10hours**

1. Pharmacology of drugs acting on cardio vascular system

a. Drug used in the therapy of shock.
b. Hematinics, coagulants and anticoagulants.
c. Fibrinolytics and anti-platelet drugs
d. Plasma volume expanders

2. Pharmacology of drugs acting on urinary system

a. Diuretics
b. Anti-diuretics.

UNIT-III **10hours**

3. Autocoids and related drugs

a. Introduction to autacoids and classification
b. Histamine, 5-HT and their antagonists.
c. Prostaglandins, Thromboxanes and Leukotrienes.
d. Angiotensin, Bradykinin and Substance P.
e. Non-steroidal anti-inflammatory agents
f. Anti-gout drugs
g. Antirheumatic drugs

UNIT-IV **08hours**

5. Pharmacology of drugs acting on endocrine system

a. Basic concepts in endocrine pharmacology.
b. Anterior Pituitary hormones- analogues and their inhibitors.
c. Thyroid hormones- analogues and their inhibitors.
d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D.
d. Insulin. Oral Hypoglycemic agents and glucagon.
e. ACTH and corticosteroids.

UNIT-V **07hours**

5. Pharmacology of drugs acting on endocrine system

a. Androgens and Anabolic steroids.
b. Estrogens, progesterone and oral contraceptives.
c. Drugs acting on the uterus.

6. Bioassay

a. Principles and applications of bioassay.
b.Types of bioassay
c. Bioassay of insulin, oxytocin, vasopressin, ACTH,d-tubocurarine,digitalis, histamine and 5-HT

BP 507 P. PHARMACOLOGY-II (Practical)

4Hrs/Week

1. Introduction to *in-vitro* pharmacology and physiological salt solutions.
2. Effect of drugs on isolated frog heart.
3. Effect of drugs on blood pressure and heart rate of dog.
4. Study of diuretic activity of drugs using rats/mice.
5. DRC of acetylcholine using frog rectus abdominis muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
7. Bioassay of histamine using guinea pig ileum by matching method.
8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11. Determination of PA_2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of PD_2 value using guinea pig ileum.
13. Effect of spasmogens and spasmolytics using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins.
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology.
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert.
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

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BP504 T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

45Hours

Scope: The main purpose of subject is to impart the students the knowledge of how the secondary metabolites are produced in the crude drugs, how to isolate and identify and produce them industrially. Also this subject involves the study of producing the plants and phytochemicals through plant tissue culture, drug interactions and basic principles of traditional system of medicine

Objectives: Upon completion of the course, the student shall be able

1. to know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents
2. to understand the preparation and development of herbal formulation.
3. to understand the herbal drug interactions
4. to carryout isolation and identification of phytoconstituents

Course Content:

UNIT-I **7 Hours**

Metabolic pathways in higher plants and their determination

a) Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway.
b) Study of utilization of radioactive isotopes in the investigation ofBiogenetic studies.

UNIT-II **14 Hours**

General introduction, composition, chemistry & chemical classes, biosources, therapeutic uses and commercial applications of following
secondary metabolites:

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium,
Phenylpropanoids and Flavonoids: Lignans, Tea, Ruta
Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis
Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander,
Tannins: Catechu, Pterocarpus
Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony
Glycosides: Senna, Aloes, Bitter Almond
Iridoids, Other terpenoids & Naphthaquinones: Gentian, Artemisia, taxus, carotenoids

UNIT-III **06 Hours**

Isolation, Identification and Analysis of Phytoconstituents

a) Terpenoids: Menthol, Citral, Artemisin
b) Glycosides: Glycyrhetinic acid & Rutin
c) Alkaloids: Atropine,Quinine,Reserpine,Caffeine
d) Resins: Podophyllotoxin, Curcumin

UNIT-IV **10 Hours**

Industrial production, estimation and utilization of the following phytoconstituents: Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine

UNIT V **8 Hours**

Basics of Phytochemistry

Modern methods of extraction, application of latest techniques like Spectroscopy, chromatography and electrophoresis in the isolation, purification and identification of crude drugs.

BP 508 P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)

4 Hours/Week

1. Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove. Ephedra, Fennel and Coriander
2. Exercise involving isolation & detection of active principles
   a. Caffeine - from tea dust.
   b. Diosgenin from Dioscorea
   c. Atropine from Belladonna
   d. Sennosides from Senna
3. Separation of sugars by Paper chromatography
4. TLC of herbal extract
5. Distillation of volatile oils and detection of phytoconstitutents by TLC
6. Analysis of crude drugs by chemical tests: (i) Asafoetida (ii) Benzoin (iii) Colophony (iv) Aloes (v) Myrrh

Recommended Books: (Latest Editions)

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Sounders & Co., London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.
12. Text Book of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R.C. Dubey.

BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)

45 Hours

Scope: This course is designed to impart basic knowledge on important legislations related to the profession of pharmacy in India.

Objectives: Upon completion of the course, the student shall be able to understand:

1. The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
2. Various Indian pharmaceutical Acts and Laws
3. The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
4. The code of ethics during the pharmaceutical practice

Course Content:

UNIT-I **10 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the Act and Rules

Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.

Manufacture of drugs – Prohibition of manufacture and sale of certain drugs,

Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

UNIT-II **10 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945.

Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA)

Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties

Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.

Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors

UNIT-III **10 Hours**

- **Pharmacy Act –1948**: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and

Penalties

- **Medicinal and Toilet Preparation Act –1955**: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.
- **Narcotic Drugs and Psychotropic substances Act-1985 and Rules**: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

UNIT-IV **08 Hours**

- **Study of Salient Features of Drugs and Magic Remedies Act and its rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties
- **Prevention of Cruelty to animals Act-1960:** Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties
- **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

UNIT-V **07 Hours**

- **Pharmaceutical Legislations** – A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee
- **Code of Pharmaceutical ethics** D efinition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath
- **Medical Termination of Pregnancy Act**
- **Right to Information Act**
- **Introduction to Intellectual Property Rights (IPR)**

Recommended books: (Latest Edition)

1. Forensic Pharmacy by B. Suresh

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2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-by M.L. Mehra
4. A text book of Forensic Pharmacy by N.K. Jain
5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
7. Narcotic drugs and psychotropic substances act by Govt. of India publications
8. Drugs and Magic Remedies act by Govt. of India publication
9.Bare Acts of the said laws published by Government. Reference books (Theory)

SEMESTER VI

BP601T. MEDICINAL CHEMISTRY – III (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasis on modern techniques of rational drug design like quantitative structure activity relationship (QSAR), Prodrug concept, combinatorial chemistry and Computer aided drug design (CADD). The subject also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

Objectives: Upon completion of the course student shall be able to

1. Understand the importance of drug design and different techniques of drug design.
2. Understand the chemistry of drugs with respect to their biological activity.
3. Know the metabolism, adverse effects and therapeutic value of drugs.
4. Know the importance of SAR of drugs.

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (*)

UNIT – I **10 Hours**

Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

β-Lactam antibiotics: Penicillin, Cepholosporins, β- Lactamase inhibitors, Monobactams

Aminoglycosides: Streptomycin, Neomycin, Kanamycin

Tetracyclines: Tetracycline,Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II **10 Hours**

Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

Macrolide: Erythromycin Clarithromycin, Azithromycin.

Miscellaneous: Chloramphenicol*, Clindamycin.

Prodrugs: Basic concepts and application of prodrugs design.

Antimalarials: Etiology of malaria.

Quinolines: SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine.

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunete, Artemether, Atovoquone.

UNIT – III **10 Hours**

Anti-tubercular Agents

Synthetic anti tubercular agents: Isoniozid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.*

Anti tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycine, Capreomycin sulphate.

Urinary tract anti-infective agents

Quinolones: SAR of quinolones, Nalidixic Acid,Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

Antiviral agents:

Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir.

UNIT – IV **08 Hours**

Antifungal agents:

Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin.

Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole, Oxiconazole Tioconozole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*.

Anti-protozoal Agents: Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.

Anthelmintics: Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin.

Sulphonamides and Sulfones

Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxaole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*.

UNIT – V **07 Hours**

Introduction to Drug Design

Various approaches used in drug design.

Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammet's electronic parameter, Tafts steric parameter and Hansch analysis.

Pharmacophore modeling and docking techniques.

Combinatorial Chemistry: Concept and applications of combinatorial chemistry: solid phase and solution phase synthesis.

BP607P. MEDICINAL CHEMISTRY- III (Practical)

4 Hours / week

I Preparation of drugs and intermediates

1 Sulphanilamide

2 7-Hydroxy, 4-methyl coumarin

3 Chlorobutanol

4 Triphenyl imidazole

5 Tolbutamide

6 Hexamine

II Assay of drugs

1 Isonicotinic acid hydrazide

2 Chloroquine

3 Metronidazole

4 Dapsone

5 Chlorpheniramine maleate

6 Benzyl penicillin

III Preparation of medicinally important compounds or intermediates by Microwave irradiation technique

IV Drawing structures and reactions using chem draw®

V Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.

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7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.

BP602 T. PHARMACOLOGY-III (Theory)

45 Hours

Scope: This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on respiratory and gastrointestinal system, infectious diseases, immuno-pharmacology and in addition,emphasis on the principles of toxicology and chronopharmacology.

Objectives: Upon completion of this course the student should be able to:

1. understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
2. comprehend the principles of toxicology and treatment of various poisoningsand
3. appreciate correlation of pharmacology with related medical sciences.

Course Content:

UNIT-I **10hours**

1. Pharmacology of drugs acting on Respiratory system

a. Anti -asthmatic drugs
b. Drugs used in the management of COPD
c. Expectorants and antitussives
d. Nasal decongestants
e. Respiratory stimulants

2. Pharmacology of drugs acting on the Gastrointestinal Tract

a. Antiulcer agents.
b. Drugs for constipation and diarrhoea.
c. Appetite stimulants and suppressants.
d. Digestants and carminatives.
e. Emetics and anti-emetics.

UNIT-II **10hours**

3. Chemotherapy

a. General principles of chemotherapy.
b. Sulfonamides and cotrimoxazole.
c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides

UNIT-III **10hours**

3. Chemotherapy

a. Antitubercular agents
b. Antileprotic agents

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c. Antifungal agents

d. Antiviral drugs

e.Anthelmintics

f. Antimalarial drugs

g. Antiamoebic agents

UNIT-IV **08hours**

3. Chemotherapy

l. Urinary tract infections and sexually transmitted diseases.

m. Chemotherapy of malignancy.

4. Immunopharmacology

a. Immunostimulants

b. Immunosuppressant

Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

UNIT-V **07hours**

5. Principles of toxicology

a. Definition and basic knowledge of acute, subacute and chronic toxicity.

b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity

c. General principles of treatment of poisoning.

d. Clinical symptoms and management of barbiturates, morphine, organophosphosphorus compound and lead, mercury and arsenic poisoning.

6. Chronopharmacology

a. Definition of rhythm and cycles.

b. Biological clock and their significance leading to chronotherapy.

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BP 608 P. PHARMACOLOGY-III (Practical)

4Hrs/Week

1. Dose calculation in pharmacological experiments
2. Antiallergic activity by mast cell stabilization assay
3. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
4. Study of effect of drugs on gastrointestinal motility
5. Effect of agonist and antagonists on guinea pig ileum
6. Estimation of serum biochemical parameters by using semi-autoanalyser
7. Effect of saline purgative on frog intestine
8. Insulin hypoglycemic effect in rabbit
9. Test for pyrogens (rabbit method)
10. Determination of acute oral toxicity (LD50) of a drug from a given data
11. Determination of acute skin irritation / corrosion of a test substance
12. Determination of acute eye irritation / corrosion of a test substance
13. Calculation of pharmacokinetic parameters from a given data
14. Biostatistics methods in experimental pharmacology(student's t test, ANOVA)
15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

**Experiments are demonstrated by simulated experiments/videos*

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,
8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
10. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

BP 603 T. HERBAL DRUG TECHNOLOGY (Theory)

45 hours

Scope: This subject gives the student the knowledge of basic understanding of herbal drug industry, the quality of raw material, guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, nutraceutical etc. The subject also emphasizes on Good Manufacturing Practices (GMP), patenting and regulatory issues of herbal drugs

Objectives: Upon completion of this course the student should be able to:

1. understand raw material as source of herbal drugs from cultivation to herbal drug product
2. know the WHO and ICH guidelines for evaluation of herbal drugs
3. know the herbal cosmetics, natural sweeteners, nutraceuticals
4. appreciate patenting of herbal drugs, GMP .

Course content:

UNIT-I **11 Hours**

Herbs as raw materials

Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation
Source of Herbs
Selection, identification and authentication of herbal materials
Processing of herbal raw material

Biodynamic Agriculture

Good agricultural practices in cultivation of medicinal plants including Organic farming.
Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

Indian Systems of Medicine

a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy
b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika,Churna, Lehya and Bhasma.

UNIT-II **7 Hours**

Nutraceuticals

General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases.
Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina

Herbal-Drug and Herb-Food Interactions: General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.

UNIT-III **10 Hours**

Herbal Cosmetics

Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.

Herbal excipients:
Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.

Herbal formulations :
Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes

UNIT- IV **10 Hours**
Evaluation of Drugs WHO & ICH guidelines for the assessment of herbal drugs
Stability testing of herbal drugs.

Patenting and Regulatory requirements of natural products:
a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.

Regulatory Issues - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

UNIT-V **07 Hours**
General Introduction to Herbal Industry
Herbal drugs industry: Present scope and future prospects.
A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.

Schedule T – Good Manufacturing Practice of Indian systems of medicine
Components of GMP (Schedule – T) and its objectives
Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.

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BP 609 P. HERBAL DRUG TECHNOLOGY (Practical)

4 hours/ week

1. To perform preliminary phytochemical screening of crude drugs.
2. Determination of the alcohol content of Asava and Arista
3. Evaluation of excipients of natural origin
4. Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.
5. Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements.
6. Monograph analysis of herbal drugs from recent Pharmacopoeias
7. Determination of Aldehyde content
8. Determination of Phenol content
9. Determination of total alkaloids

Recommended Books: (Latest Editions)

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale
4. Essential of Pharmacognosy by Dr.S.H.Ansari
5. Pharmacognosy & Phytochemistry by V.D.Rangari
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.

BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS
(Theory)

45 Hours

Scope: This subject is designed to impart knowledge and skills of Biopharmaceutics and pharmacokinetics and their applications in pharmaceutical development, design of dose and dosage regimen and in solving the problems arised therein.

Objectives: Upon completion of the course student shall be able to:

1. Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.
2. Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
3. To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
4. Understand various pharmacokinetic parameters, their significance & applications.

Course Content:

UNIT-I **10 Hours**

Introduction to Biopharmaceutics

Absorption; Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non per oral extra-vascular routes, **Distribution** Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

UNIT- II **10 Hours**

Elimination: Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs

Bioavailability and Bioequivalence: Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, *in-vitro* drug dissolution models, *in-vitro-in-vivo* correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs.

UNIT- III **10 Hours**

Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters - K_E ,t1/2,Vd,AUC,Ka, Clt and CL_R- definitions methods of eliminations, understanding of their significance and application

UNIT- IV **08 Hours**

Multicompartment models: Two compartment open model. IV bolus
Kinetics of multiple dosing, steady state drug levels, calculation of loading and mainetnance doses and their significance in clinical settins.

UNIT- V **07 Hours**

Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity.
c. Michaelis-menton method of estimating parameters, Explanation with example of drugs.

Recommended Books: (Latest Editions)

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition,Prentice-Hall Inernational edition.USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal,Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company,Pennsylvania 1989.
11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
12. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia

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Hanamkonda, Warangal-506 001

BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)

45 Hours

Scope:

- Biotechnology has a long promise to revolutionize the biological sciences and technology.
- Scientific application of biotechnology in the field of genetic engineering, medicine and fermentation technology makes the subject interesting.
- Biotechnology is leading to new biological revolutions in diagnosis, prevention and cure of diseases, new and cheaper pharmaceutical drugs.
- Biotechnology has already produced transgenic crops and animals and the future promises lot more.
- It is basically a research-based subject.

Objectives: Upon completion of the subject student shall be able to;

1. Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
2. Genetic engineering applications in relation to production of pharmaceuticals
3. Importance of Monoclonal antibodies in Industries
4. Appreciate the use of microorganisms in fermentation technology

Unit I **10 Hours**

a) Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.

b) Enzyme Biotechnology- Methods of enzyme immobilization and applications.

c) Biosensors- Working and applications of biosensors in Pharmaceutical Industries.

d) Brief introduction to Protein Engineering.

e) Use of microbes in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.

f) Basic principles of genetic engineering.

Unit II **10 Hours**

a) Study of cloning vectors, restriction endonucleases and DNA ligase.

b) Recombinant DNA technology. Application of genetic engineering in medicine.

c) Application of r DNA technology and genetic engineering in the production of:

i) Interferon ii) Vaccines- hepatitis- B iii) Hormones-Insulin.

d) Brief introduction to PCR

Unit III **10 Hours**

Types of immunity- humoral immunity, cellular immunity

a) Structure of Immunoglobulins
b) Structure and Function of MHC
c) Hypersensitivity reactions, Immune stimulation and Immune suppressions.
d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.
e) Storage conditions and stability of official vaccines
f) Hybridoma technology- Production, Purification and Applications
g) Blood products and Plasma Substituties.

Unit IV **08Hours**

a) Immuno blotting techniques- ELISA, Western blotting, Southern blotting.
b) Genetic organization of Eukaryotes and Prokaryotes
c) Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.
d) Introduction to Microbial biotransformation and applications.
e) Mutation: Types of mutation/mutants.

Unit V **07 Hours**

a) Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.
b) Large scale production fermenter design and its various controls.
c) Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin,
d) Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substituties.

Recommended Books (Latest edition):

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
2. RA Goldshy et. al., : Kuby Immunology.
3. J.W. Goding: Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal

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Hanamkonda, Warangal

Society of Chemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

BP606TPHARMACEUTICAL QUALITY ASSURANCE (Theory)

45 Hours

Scope: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

Objectives: Upon completion of the course student shall be able to:

- understand the cGMP aspects in a pharmaceutical industry
- appreciate the importance of documentation
- understand the scope of quality certifications applicable to pharmaceutical industries
- understand the responsibilities of QA & QC departments

Course content:

UNIT – I **10 Hours**

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP

Total Quality Management (TQM): Definition, elements, philosophies

ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines

Quality by design (QbD): Definition, overview, elements of QbD program, tools

ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration

NABL accreditation : Principles and procedures

UNIT - II **10 Hours**

Organization and personnel: Personnel responsibilities, training, hygiene and personal records.

Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

Equipments and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

UNIT – III **10 Hours**

Quality Control: Quality control test for containers, rubber closures and secondary packing

materials.

Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities

UNIT – IV **08 Hours**

Complaints: Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.

Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

UNIT – V **07 Hours**

Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.

Warehousing: Good warehousing practice, materials management

Recommended Books: (Latest Edition)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total Quality Management – Sadhank G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Deckker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines

SEMESTER VII

BP701T. INSTRUMENTAL METHODS OF ANALYSIS (Theory)

45 Hours

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart a fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic technique. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

Objectives: Upon completion of the course the student shall be able to

1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
2. Understand the chromatographic separation and analysis of drugs.
3. Perform quantitative & qualitative analysis of drugs using various analytical instruments.

Course Content:

UNIT –I **10 Hours**

UV Visible spectroscopy

Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.

Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors- Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications - Spectrophotometric titrations, Single component and multi component analysis

Fluorimetry

Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications

UNIT –II **10 Hours**

IR spectroscopy

Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations

Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications

Flame Photometry-Principle, interferences, instrumentation and applications

Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications

Nepheloturbidometry- Principle, instrumentation and applications

UNIT –III **10 Hours**

Introduction to chromatography

Adsorption and partition column chromatography-Methodology, advantages, disadvantages and applications.

Thin layer chromatography- Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.

Paper chromatography-Introduction, methodology, development techniques, advantages, disadvantages and applications

Electrophoresis– Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications

UNIT –IV **08 Hours**

Gas chromatography - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications

High performance liquid chromatography (HPLC)-Introduction, theory, instrumentation, advantages and applications.

UNIT –V **07 Hours**

Ion exchange chromatography- Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications

Gel chromatography- Introduction, theory, instrumentation and applications

Affinity chromatography- Introduction, theory, instrumentation and applications

BP705P. INSTRUMENTAL METHODS OF ANALYSIS (Practical)

4 Hours/Week

1 Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
2 Estimation of dextrose by colorimetry
3 Estimation of sulfanilamide by colorimetry
4 Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
5 Assay of paracetamol by UV-Spectrophotometry
6 Estimation of quinine sulfate by fluorimetry
7 Study of quenching of fluorescence
8 Determination of sodium by flame photometry
9 Determination of potassium by flame photometry
10 Determination of chlorides and sulphates by nephelo turbidometry
11 Separation of amino acids by paper chromatography
12 Separation of sugars by thin layer chromatography
13 Separation of plant pigments by column chromatography
14 Demonstration experiment on HPLC
15 Demonstration experiment on Gas Chromatography

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

BP 702 T. INDUSTRIAL PHARMACYII (Theory)

45 Hours

Scope: This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market

Objectives: Upon completion of the course, the student shall be able to:

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different Laws and Acts that regulate pharmaceutical industry
4. Understand the approval process and regulatory requirements for drug products

Course Content:

UNIT-I **10 Hours**

Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

UNIT-II **10 Hours**

Technology development and transfer: WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues

UNIT-III **10 Hours**

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals

Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

UNIT-IV **08 Hours**

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

UNIT-V **07 Hours**

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

Recommended Books: (Latest Editions)

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http,//en.wikipedia.org/wiki/Regulatory_ Affairs.
2. International Regulatory Affairs Updates, 2005. available at http://www.iraup.com/about.php
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc. available at http.//www.cgmp.com/ra.htm.

BP 703T. PHARMACY PRACTICE (Theory)

45 Hours

Scope: In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the community set up.

Objectives: Upon completion of the course, the student shall be able to

1. know various drug distribution methods in a hospital
2. appreciate the pharmacy stores management and inventory control
3. monitor drug therapy of patient through medication chart review and clinical review
4. obtain medication history interview and counsel the patients
5. identify drug related problems
6. detect and assess adverse drug reactions
7. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
8. know pharmaceutical care services
9. do patient counseling in community pharmacy;
10. appreciate the concept of Rational drug therapy.

Unit I: **10 Hours**

a) Hospital and it's organization

Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non- clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions.

b) Hospital pharmacy and its organization

Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.

c) Adverse drug reaction

Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting

drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management.

d) Community Pharmacy

Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.

Unit II: **10 Hours**

a) Drug distribution system in a hospital

Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, Dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs.

b) Hospital formulary

Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary.

c) Therapeutic drug monitoring

Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.

d) Medication adherence

Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence.

e) Patient medication history interview

Need for the patient medication history interview, medication interview forms.

f) Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

Unit III: **10 Hours**

a) Pharmacy and therapeutic committee

Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation.

b) Drug information services

Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.

c) **Patient counseling**

Definition of patient counseling; steps involved in patient counseling, and Special cases that require the pharmacist

d) **Education and training program in the hospital**

Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education.

e) **Prescribed medication order and communication skills**

Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.

Unit IV **8 Hours**

a) **Budget preparation and implementation**

Budget preparation and implementation

b) **Clinical Pharmacy**

Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care.

Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern.

c) **Over the counter (OTC) sales**

Introduction and sale of over the counter, and Rational use of common over the counter medications.

Unit V **7 Hours**

a) **Drug store management and inventory control**

Organisation of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure

b) **Investigational use of drugs**

Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee.

c) Interpretation of Clinical Laboratory Tests

Blood chemistry, hematology, and urinalysis

Recommended Books (Latest Edition):

1. Merchant S.H. and Dr. J.S.Quadry. *A textbook of hospital pharmacy*, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. *A textbook of Clinical Pharmacy Practice- essential concepts and skills,* 1st ed. Chennai: Orient Longman Private Limited; 2004.
3. William E. Hassan. *Hospital pharmacy*, 5th ed. Philadelphia: Lea & Febiger; 1986.
4. Tipnis Bajaj. *Hospital Pharmacy*, 1st ed. Maharashtra: Career Publications; 2008.
5. Scott LT. *Basic skills in interpreting laboratory data*, 4thed. American Society of Health System Pharmacists Inc; 2009.
6. Parmar N.S. *Health Education and Community Pharmacy,* 18th ed. India: CBS Publishers & Distributers; 2008.

Journals:

1. Therapeutic drug monitoring. ISSN: 0163-4356
2. Journal of pharmacy practice. ISSN : 0974-8326
3. American journal of health system pharmacy. ISSN: 1535-2900 (online)
4. Pharmacy times (Monthly magazine)

BP 704T: NOVEL DRUG DELIVERY SYSTEMS (Theory)

45 Hours

Scope: This subject is designed to impart basic knowledge on the area of novel drug delivery systems.

Objectives: Upon completion of the course student shall be able

1. To understand various approaches for development of novel drug delivery systems.
2. To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

Course content:

Unit-I **10 Hours**

Controlled drug delivery systems: Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates.Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations

Polymers: Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.

Unit-II **10 Hours**

Microencapsulation: Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications

Mucosal Drug Delivery system: Introduction, Principles of bioadhesion / mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems

Implantable Drug Delivery Systems: Introduction, advantages and disadvantages, concept of implantsand osmotic pump

Unit-III **10 Hours**

Transdermal Drug Delivery Systems: Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches

Gastroretentive drug delivery systems: Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesive systems and their applications

Nasopulmonary drug delivery system: Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers

Unit-IV **08 Hours**

Targeted drug Delivery: Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

Unit-V **07 Hours**

Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to overcome –Preliminary study, ocular formulations and ocuserts

Intrauterine Drug Delivery Systems: Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications

Recommended Books: (Latest Editions)

1. Y. W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

Journals

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian Drugs (IDMA)
3. Journal of Controlled Release (Elsevier Sciences)
4. Drug Development and Industrial Pharmacy (Marcel & Decker)
5. International Journal of Pharmaceutics (Elsevier Sciences)

SEMESTER VIII

BP801T. BIOSTATISITCS AND RESEARCH METHODOLOGY (Theory)

45 Hours

Scope: To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel.

Objectives: Upon completion of the course the student shall be able to

- Know the operation of M.S. Excel, SPSS, R and MINITAB®, DoE (Design of Experiment)
- Know the various statistical techniques to solve statistical problems
- Appreciate statistical techniques in solving the problems.

Course content:

Unit-I **10 Hours**

Introduction: Statistics, Biostatistics, Frequency distribution

Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples

Measures of dispersion: Dispersion, Range, standard deviation, Pharmaceutical problems

Correlation: Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples

Unit-II **10 Hours**

Regression: Curve fitting by the method of least squares, fitting the lines y= a + bx and x = a + by, Multiple regression, standard error of regression– Pharmaceutical Examples

Probability: Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties - problems

Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples

Parametric test: t-test(Sample, Pooled or Unpaired and Paired) , ANOVA, (One way and Two way), Least Significance difference

Unit-III **10 Hours**

Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test

Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism

Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph

Designing the methodology: Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

Unit-IV **8 Hours**

Blocking and confounding system for Two-level factorials

Regression modeling: Hypothesis testing in Simple and Multiple regressionmodels

Introduction to Practical components of Industrial and Clinical Trials Problems: Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach

Unit-V **7Hours**

Design and Analysis of experiments:

Factorial Design: Definition, 2^2, 2^3design. Advantage of factorial design

Response Surface methodology: Central composite design, Historical design, Optimization Techniques

Recommended Books (Latest edition):

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork.
2. Fundamental of Statistics – Himalaya Publishing House- S.C.Guptha
3. Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam,
4. Design and Analysis of Experiments – Wiley Students Edition, Douglas and C. Montgomery

BP 802T SOCIAL AND PREVENTIVE PHARMACY

Hours: 45

Scope:
The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health programmes. The roles of the pharmacist in these contexts are also discussed.

Objectives:
After the successful completion of this course, the student shall be able to:

- Acquire high consciousness/realization of current issuesrelated to health and pharmaceutical problems within the country and worldwide.
- Have a critical way of thinking based on current healthcare development.
- Evaluate alternative ways of solving problems related tohealth and pharmaceutical issues

Course content:

Unit I: **10 Hours**

Concept of health and disease: Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.

Social and health education: Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.

Sociology and health: Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health

Hygiene and health: personal hygiene and health care; avoidable habits

Unit II: **10 Hours**

Preventive medicine: General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse

Unit III: **10 Hours**

National health programs, its objectives, functioning and outcome of the following: HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National

programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

Unit IV: **08 Hours**

National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program

Unit V: **07 Hours**

Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.

Recommended Books (Latest edition):

1. Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
4. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
5. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.
6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

Recommended Journals:

1. Research in Social and Administrative Pharmacy, Elsevier, Ireland

Principal
Vaagdevi College of Pharmacy
Hanamkonda, Warangal

BP803ET. PHARMA MARKETING MANAGEMENT (Theory)

45 Hours

Scope:
The pharmaceutical industry not only needs highly qualified researchers, chemists and, technical people, but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Product management.

Course Objective: The course aims to provide an understanding of marketing concepts and techniques and their applications in the pharmaceutical industry.

Unit I **10 Hours**

Marketing:
Definition, general concepts and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior.

Pharmaceutical market:
Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation& targeting.Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist.Analyzing the Market;Role of market research.

Unit II **10 Hours**

Product decision:
Classification, product line and product mix decisions, product life cycle,product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

Unit III **10 Hours**

Promotion:
Methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.

Unit IV **10 Hours**

Pharmaceutical marketing channels:

Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.

Professional sales representative (PSR):

Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

Unit V **10 Hours**

Pricing:

Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order)and NPPA (National Pharmaceutical Pricing Authority).

Emerging concepts in marketing:

Vertical & Horizontal Marketing; RuralMarketing; Consumerism; Industrial Marketing; Global Marketing.

Recommended Books: (Latest Editions)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt:Global Perspective, IndianContext,Macmilan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

BP804 ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory)

45Hours

Scope: This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia,UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

Objectives: Upon completion of the subject student shall be able to;

1. Know about the process of drug discovery and development
2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
3. Know the regulatory approval process and their registration in Indian and international markets

Course content:

Unit I **10Hours**

New Drug Discovery and development

Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

Unit II **10Hours**

Regulatory Approval Process

Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.

Regulatory authorities and agencies

Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

Unit III **10Hours**

Registration of Indian drug product in overseas market

Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical

Document (eCTD), ASEAN Common Technical Document (ACTD)research.

Unit IV **08Hours**

Clinical trials

Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials

Unit V **07Hours**

Regulatory Concepts

Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

Recommended books (Latest edition):

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, Second Edition By Rick Ng

BP 805T: PHARMACOVIGILANCE (Theory)

45 hours

Scope: This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

Objectives:

At completion of this paper it is expected that students will be able to (know, do, and appreciate):

1. Why drug safety monitoring is important?
2. History and development of pharmacovigilance
3. National and international scenario of pharmacovigilance
4. Dictionaries, coding and terminologies used in pharmacovigilance
5. Detection of new adverse drug reactions and their assessment
6. International standards for classification of diseases and drugs
7. Adverse drug reaction reporting systems and communication in pharmacovigilance
8. Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle
9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
10. Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India
11. ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning
12. CIOMS requirements for ADR reporting
13. Writing case narratives of adverse events and their quality.

Course Content

Unit I **10 Hours**

Introduction to Pharmacovigilance

- History and development of Pharmacovigilance
- Importance of safety monitoring of Medicine
- WHO international drug monitoring programme
- Pharmacovigilance Program of India(PvPI)

Introduction to adverse drug reactions

- Definitions and classification of ADRs
- Detection and reporting
- Methods in Causality assessment
- Severity and seriousness assessment
- Predictability and preventability assessment
- Management of adverse drug reactions

Basic terminologies used in pharmacovigilance

- Terminologies of adverse medication related events
- Regulatory terminologies

Unit II **10 hours**

Drug and disease classification

- Anatomical, therapeutic and chemical classification of drugs
- International classification of diseases
- Daily defined doses
- International Non proprietary Names for drugs

Drug dictionaries and coding in pharmacovigilance

- WHO adverse reaction terminologies
- MedDRA and Standardised MedDRA queries
- WHO drug dictionary
- Eudravigilance medicinal product dictionary

Information resources in pharmacovigilance

- Basic drug information resources
- Specialised resources for ADRs

Establishing pharmacovigilance programme

- Establishing in a hospital
- Establishment & operation of drug safety department in industry
- Contract Research Organisations (CROs)
- Establishing a national programme

Unit III **10 Hours**

Vaccine safety surveillance

- Vaccine Pharmacovigilance
- Vaccination failure
- Adverse events following immunization

Pharmacovigilance methods

- Passive surveillance – Spontaneous reports and case series
- Stimulated reporting
- Active surveillance – Sentinel sites, drug event monitoring and registries
- Comparative observational studies – Cross sectional study, case control study and cohort study
- Targeted clinical investigations

Communication in pharmacovigilance

- Effective communication in Pharmacovigilance
- Communication in Drug Safety Crisis management
- Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media

Unit IV **8 Hours**

Safety data generation

- Pre clinical phase
- Clinical phase
- Post approval phase (PMS)

ICH Guidelines for Pharmacovigilance

- Organization and objectives of ICH
- Expedited reporting
- Individual case safety reports
- Periodic safety update reports
- Post approval expedited reporting
- Pharmacovigilance planning
- Good clinical practice in pharmacovigilance studies

Unit V **7 hours**

Pharmacogenomics of adverse drug reactions

- Genetics related ADR with example focusing PK parameters.

Drug safety evaluation in special population

- Paediatrics
- Pregnancy and lactation
- Geriatrics

CIOMS

- CIOMS Working Groups
- CIOMS Form

CDSCO (India) and Pharmacovigilance

- D&C Act and Schedule Y
- Differences in Indian and global pharmacovigilance requirements

Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance:Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller,Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert,Jones& Bartlett Publishers.
7. Textbook of Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy,Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills:G. Parthasarathi, Karin NyfortHansen,Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna

12. http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297
13. http://www.ich.org/
14. http://www.cioms.ch/
15. http://cdsco.nic.in/
16. http://www.who.int/vaccine_safety/en/
17. http://www.ipc.gov.in/PvPI/pv_home.html

BP 806 ET. QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory)

Scope: In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.

Objectives: Upon completion of the subject student shall be able to;

1. know WHO guidelines for quality control of herbal drugs
2. know Quality assurance in herbal drug industry
3. know the regulatory approval process and their registration in Indian and international markets
4. appreciate EU and ICH guidelines for quality control of herbal drugs

Unit I **10 hours**

Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms

WHO guidelines for quality control of herbal drugs.

Evaluation of commercial crude drugs intended for use

Unit II **10 hours**

Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine.

WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines

WHO Guidelines on GACP for Medicinal Plants.

Unit III **10 hours**

EU and ICH guidelines for quality control of herbal drugs.

Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

Unit IV **08 hours**

Stability testing of herbal medicines.Application of various chromatographic techniques in standardization of herbal products.

Preparation of documents for new drug application and export registration

GMP requirements and Drugs & Cosmetics Act provisions.

Unit V **07 hours**

Regulatory requirements for herbal medicines.

WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems

Comparison of various Herbal Pharmacopoeias.

Role of chemical and biological markers in standardization of herbal products

Recommended Books: (Latest Editions

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
12. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

BP 807 ET. COMPUTER AIDED DRUG DESIGN (Theory)

45 Hours

Scope: This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

Objectives: Upon completion of the course, the student shall be able to understand

- Design and discovery of lead molecules
- The role of drug design in drug discovery process
- The concept of QSAR and docking
- Various strategies to develop new drug like molecules.
- The design of new drug molecules using molecular modeling software

Course Content:

UNIT-I **10 Hours**

Introduction to Drug Discovery and Development

Stages of drug discovery and development

Lead discovery and Analog Based Drug Design

Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.

Analog Based Drug Design: Bioisosterism, Classification, Bioisosteric replacement. Any three case studies

UNIT-II **10 Hours**

Quantitative Structure Activity Relationship (QSAR)

SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

UNIT-III **10 Hours**

Molecular Modeling and virtual screening techniques

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

Molecular docking: Rigid docking, flexible docking, manual docking, Docking based screening. *De novo* drug design.

UNIT-IV **08 Hours**

Informatics & Methods in drug design

Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

UNIT-V **07 Hours**

Molecular Modeling: Introduction to molecular mechanics and quantum mechanics.Energy Minimization methods and Conformational Analysis, global conformational minima determination.

Recommended Books (Latest Editions)

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry 'Lea & Febiger.
5. Koro Ikovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.

BP808ET: CELL AND MOLECULAR BIOLOGY (Elective subject)

45 Hours

Scope:

- Cell biology is a branch of biology that studies cells – their physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cell function.
- This is done both on a microscopic and molecular level.
- Cell biology research encompasses both the great diversity of single-celled organisms like bacteria and protozoa, as well as the many specialized cells in multi-cellular organismssuch as humans, plants, and sponges.

Objectives: Upon completion of the subject student shall be able to;

- Summarize cell and molecular biology history.
- Summarize cellular functioning and composition.
- Describe the chemical foundations of cell biology.
- Summarize the DNA properties of cell biology.
- Describe protein structure and function.
- Describe cellular membrane structure and function.
- Describe basic molecular genetic mechanisms.
- Summarize the Cell Cycle

Course content:

Unit I **10Hours**

a) Cell and Molecular Biology: Definitions theory and basics and Applications.
b) Cell and Molecular Biology: History and Summation.
c) Properties of cells and cell membrane.
d) Prokaryotic versus Eukaryotic
e) Cellular Reproduction
f) Chemical Foundations – an Introduction and Reactions (Types)

Unit II **10 Hours**

a) DNA and the Flow of Molecular Information
b) DNA Functioning
c) DNA and RNA
d) Types of RNA
e) Transcription and Translation

Unit III **10 Hours**

a) Proteins: Defined **and** Amino Acids
b) Protein Structure

c) Regularities in Protein Pathways
d) Cellular Processes
e) Positive Control and significance of Protein Synthesis

Unit IV **08 Hours**

a) Science of Genetics
b) Transgenics and Genomic Analysis
c) Cell Cycle analysis
d) Mitosis and Meiosis
e) Cellular Activities and Checkpoints

Unit V **07 Hours**

a) Cell Signals: Introduction
b) Receptors for Cell Signals
c) Signaling Pathways: Overview
d) Misregulation of Signaling Pathways
e) Protein-Kinases: Functioning

Recommended Books (latest edition):

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. Edward: Fundamentals of Microbiology.
10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
13. RA Goldshy et. al., : Kuby Immunology.

BP809ET. COSMETIC SCIENCE(Theory)

45Hours

UNIT I **10Hours**

Classification of cosmetic and cosmeceutical products

Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs

Cosmetic excipients: Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application

Skin: Basic structure and function of skin.

Hair: Basic structure of hair. Hair growth cycle.

Oral Cavity: Common problem associated with teeth and gums.

UNIT II **10 Hours**

Principles of formulation and building blocks of skin care products:

Face wash,

Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages.Application of these products in formulation of cosmecuticals.

Antiperspants & deodorants- Actives & mechanism of action.

Principles of formulation and building blocks of Hair care products:

Conditioning shampoo, Hair conditioner,anti-dandruff shampoo.

Hair oils.

Chemistry and formulation of Para-phylene diamine based hair dye.

Principles of formulation and building blocks of oral care products:

Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

UNIT III **10 Hours**

Sun protection, Classification of Sunscreens and SPF.

Role of herbs in cosmetics:

Skin Care: Aloe and turmeric

Hair care: Henna and amla.

Oral care: Neem and clove

Analytical cosmetics: BIS specification and analytical methods for shampoo, skin-cream and toothpaste.

UNIT IV **08 Hours.**

Principles of Cosmetic Evaluation:Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties

Soaps,and syndet bars. Evolution and skin benfits.

UNIT V **07 Hours**

Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis.

Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes

Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor.

Antiperspirants and Deodorants- Actives and mechanism of action

References

1) Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
2) Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.
3) Text book of cosmelicology by Sanju Nanda & Roop K. Khar, Tata Publishers.

BP810 ET. PHARMACOLOGICAL SCREENING METHODS

45 Hours

Scope: This subject is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

Objectives

Upon completion of the course the student shall be able to,

- Appreciate the applications of various commonly used laboratory animals.
- Appreciate and demonstrate the various screening methods used in preclinical research
- Appreciate and demonstrate the importance of biostatistics and researchmethodology
- Design and execute a research hypothesis independently

Unit –I	**08 Hours**
Laboratory Animals: Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.	
Unit –II	**10 Hours**
Preclinical screening models a. Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study. b. **Study of screening animal models for** Diuretics, nootropics, anti-Parkinson's,antiasthmatics, **Preclinical screening models:** for CNS activity- analgesic, antipyretic,anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease	

Unit –III **Preclinical screening models:** for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaethetics	
Unit –IV **Preclinical screening models:** for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.	
Research methodology and Bio-statistics Selection of research topic, review of literature, research hypothesis and study design Pre-clinical data analysis and interpretation using Students 't' test and One-way ANOVA. Graphical representation of data	**05 Hours**

Recommended Books (latest edition):

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. CPCSEA guidelines for laboratory animal facility.
4. Drug discovery and Evaluation by Vogel H.G.
5. Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta
6. Introduction to biostatistics and research methods by PSS Sundar Rao and J Richard

BP 811 ET. ADVANCED INSTRUMENTATION TECHNIQUES

45 Hours

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

Objectives: Upon completion of the course the student shall be able to

- understand the advanced instruments used and its applications in drug analysis
- understand the chromatographic separation and analysis of drugs.
- understand the calibration of various analytical instruments
- know analysis of drugs using various analytical instruments.

Course Content:

UNIT-I **10 Hours**

Nuclear Magnetic Resonance spectroscopy

Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications

Mass Spectrometry- Principles, Fragmentation, Ionization techniques – Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications

UNIT-II **10 Hours**

Thermal Methods of Analysis: Principles, instrumentation and applications of ThermogravimetricAnalysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC)

X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, X-ray

Crystallography, rotating crystal technique, single crystal diffraction,powder diffraction, structural elucidation and applications.

UNIT-III **10 Hours**

Calibration and validation-as per ICH and USFDA guidelines

Calibration of following Instruments

Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer,

Fluorimeter, Flame Photometer, HPLC and GC

UNIT-IV **08 Hours**

Radio immune assay: Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay

Extraction techniques: General principle and procedure involved in the solid phase extraction and liquid-liquid extraction

UNIT-V **07 Hours**

Hyphenated techniques-LC-MS/MS, GC-MS/MS, HPTLC-MS.

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

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BP 812 ET. DIETARY SUPPLEMENTS AND NUTRACEUTICALS

No. of hours :3 **Tutorial:1** **Credit point:4**

Scope :

This subject covers foundational topic that are important for understanding the need and requirements of dietary supplements among different groups in the population.

Objective:

This module aims to provide an understanding of the concepts behind the theoretical applications of dietary supplements. By the end of the course, students should be able to :

1. Understand the need of supplements by the different group of people to maintain healthy life.
2. Understand the outcome of deficiencies in dietary supplements.
3. Appreciate the components in dietary supplements and the application.
4. Appreciate the regulatory and commercial aspects of dietary supplements including health claims.

UNIT I **07 hours**

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc.
b. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community.
c. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT II **15 hours**

Phytochemicals as nutraceuticals: Occurrence and characteristic features(chemical nature medicinal benefits) of following

a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, leutin
b) Sulfides: Diallyl sulfides, Allyl trisulfide.
c) Polyphenolics: Reservetrol
d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones
e) Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum
f) Phyto estrogens : Isoflavones, daidzein, Geebustin, lignans
g) Tocopherols
h) Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.

UNIT III **07 hours**

a) Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids

b) Dietary fibres and complex carbohydrates as functional food ingredients..

UNIT IV **10 hours**

a) Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage. muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.

b) Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin
Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.

c) Functional foods for chronic disease prevention

UNIT V **06 hours**

a) Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.

b) Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.

c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

References:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPunblication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2nd Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C.williams Editors *2000 Functional foods* Woodhead Publ.Co.London.
7. Goldberg, I. *Functional Foods.* 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

Semester VIII – Elective course on Pharmaceutical Product Development

No of Hours: 3 Tutorial:1 Credit points:4

Unit-I **10 Hours**

Introduction to pharmaceutical product development, objectives, regulations related to preformulation, formulation development, stability assessment, manufacturing and quality control testing of different types of dosage forms

Unit-II **10 Hours**

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

i. Solvents and solubilizers
ii. Cyclodextrins and their applications
iii. Non - ionic surfactants and their applications
iv. Polyethylene glycols and sorbitols
v. Suspending and emulsifying agents
vi. Semi solid excipients

Unit-III **10 Hours**

An advanced study of Pharmaceutical Excipients in pharmaceutical product development with a special reference to the following categories

i. Tablet and capsule excipients
ii. Directly compressible vehicles
iii. Coat materials
iv. Excipients in parenteral and aerosols products
v. Excipients for formulation of NDDS

Selection and application of excipients in pharmaceutical formulations with specific industrial applications

Unit-IV **08 Hours**

Optimization techniques in pharmaceutical product development.A study of various optimization techniques for pharmaceutical product development with specific examples.Optimization by factorial designs and their applications.A study of QbD and its application in pharmaceutical product development.

Unit-V **07 Hours**

Selection and quality control testing of packaging materials for pharmaceutical product development- regulatory considerations.

Recommended Books (Latest editions)

1. Pharmaceutical Statistics Practical and Clinical Applications byStanford Bolton, CharlesBon; Marcel Dekker Inc.
2. Encyclopedia of Pharmaceutical Technology, edited by James swarbrick,Third Edition,Informa Healthcare publishers.
3. Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman andLeon Lachman; Marcel Dekker, Inc.
4. The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by Roop kKhar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt.Ltd. 2013.
5. Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, BI Publications Pvt. Ltd.
6. Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyas and R. K.Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012.
7. Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen Jr., Nicholas B.Popovich, Howard C. Ansel, 9th Ed. 40
8. Aulton's Pharmaceutics – The Design and Manufacture of Medicines, Michael E. Aulton,3rd Ed.
9. Remington – The Science and Practice of Pharmacy, 20th Ed.
10. Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon Lachman andJoseph B. Schwartz
11. Pharmaceutical Dosage Forms – Disperse Systems Vol 1 to 3, H.A. Liberman, Martin, M.R and Gilbert S. Banker.
12. Pharmaceutical Dosage Forms – Parenteral Medication Vol 1 & 2, Kenneth E. Avis andH.A. Libermann.
13. Advanced Review Articles related to the topics.

रजिस्ट्री सं. डीएल (एन)-04/0007/2003--05 REGISTERED No. DL(N)—04/0007/2003—05

भारत का राजपत्र
The Gazette of India

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इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।
(Separate paging is given to this Part in order that it may be filed as a separate compilation)

भाग III—खण्ड 4
[PART III—SECTION 4]
[सांविधिक निकायों द्वारा जारी की गई विविध अधिसूचनाएं जिसमें कि आदेश, विज्ञापन और सूचनाएं सम्मिलित हैं]
[Miscellaneous Notifications including Notifications, Orders, Advertisements and Notices issued by Statutory Bodies]

भारतीय रिज़र्व बैंक

मुंबई-400001, दिनांक 9 अप्रैल 2008

सदर्भ : बैंपविवि. सं. आईबीडी.-14241/23.13.048/2007-08--भारतीय रिज़र्व बैंक अधिनियम, 1934 (1934 का 2) की धारा 42 की उप--धारा (6) के खण्ड (ग) के अनुसरण में भारतीय रिज़र्व बैंक इसके द्वारा निदेश देता है कि उक्त अधिनियम की दूसरी अनुसूची में निम्नलिखित परिवर्तन किये जाएं :--

''अरब बांगलादेश बैंक लिमिटेड'' शब्दों के स्थान पर ''एबी बैंक लिमिटेड'' शब्द होंगे।

आनन्द सिन्हा
कार्यपालक निदेशक

[PUBLISHED IN THE GAZETTE OF INDIA, No.19, PART III, SECTION 4]

Ministry of Health and Family Welfare
(Pharmacy Council of India)

New Delhi, 10th May, 2008.

Pharm.D. Regulations 2008

Regulations framed under section 10 of the Pharmacy Act, 1948 (8 of 1948).

(As approved by the Government of India, Ministry of Health vide, letter No.V.13013/1/2007-PMS, dated the 13th March, 2008 and notified by the Pharmacy Council of India).

No.14-126/2007-PCI.— In exercise of the powers conferred by section 10 of the Pharmacy Act, 1948 (8 of 1948), the Pharmacy Council of India, with the approval of the Central Government, hereby makes the following regulations, namely:-

CHAPTER-I

1. Short title and commencement. – (1) These regulations may be called the Pharm.D. Regulations 2008.

   (2) They shall come into force from the date of their publication in the official Gazette.

2. Pharm.D. shall consist of a certificate, having passed the course of study and examination as prescribed in these regulations, for the purpose of registration as a pharmacist to practice the profession under the Pharmacy Act, 1948.

CHAPTER-II

3. Duration of the course. –

a) Pharm.D: The duration of the course shall be six academic years (five years of study and one year of internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of six years duration is divided into two phases –

Phase I – consisting of First, Second, Third, Fourth and Fifth academic year.

Phase II – consisting of internship or residency training during sixth year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services and acquires skill under supervision so that he or she may become capable of functioning independently.

b) Pharm.D. (Post Baccalaureate): The duration of the course shall be for three academic years (two years of study and one year internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of three years duration is divided into two phases –

Phase I – consisting of First and Second academic year.
Phase II – consisting of Internship or residency training during third year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services, and acquires skill under supervision so that he or she may become capable of functioning independently.

4. Minimum qualification for admission to. –

a) Pharm.D. Part-I Course – A pass in any of the following examinations -

(1) 10+2 examination with Physics and Chemistry as compulsory subjects along with one of the following subjects:

Mathematics or Biology.

(2) A pass in D.Pharm course from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act.

(3) Any other qualification approved by the Pharmacy Council of India as equivalent to any of the above examinations.

Provided that a student should complete the age of 17 years on or before 31st December of the year of admission to the course.

Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

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b) Pharm.D. (Post Baccalaureate) Course -

A pass in B.Pharm from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act:

Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

5. Number of admissions in the above said programmes shall be as prescribed by the Pharmacy Council of India from time to time and presently be restricted as below –
   i) Pharm.D. Programme – 30 students.
   ii) Pharm.D. (Post Baccalaureate) Programme – 10 students.

6. Institutions running B.Pharm programme approved under section 12 of the Pharmacy Act, will only be permitted to run Pharm.D. programme. Pharm.D. (Post Baccalaureate) programme will be permitted only in those institutions which are permitted to run Pharm.D. programme.

7. Course of study. – The course of study for Pharm.D. shall include the subjects as given in the Tables below. The number of hours in a week, devoted to each subject for its teaching in theory, practical and tutorial shall not be less than that noted against it in columns (3), (4) and (5) below.

TABLES

First Year :

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
1.1	Human Anatomy and Physiology	3	3	1
1.2	Pharmaceutics	2	3	1
1.3	Medicinal Biochemistry	3	3	1
1.4	Pharmaceutical Organic Chemistry	3	3	1
1.5	Pharmaceutical Inorganic Chemistry	2	3	1
1.6	Remedial Mathematics/ Biology	3	3*	1
	Total hours	**16**	**18**	**6 = (40)**

* For Biology

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Second Year:

S.No	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
2.1	Pathophysiology	3	-	1
2.2	Pharmaceutical Microbiology	3	3	1
2.3	Pharmacognosy & Phytopharmaceuticals	3	3	1
2.4	Pharmacology-I	3	-	1
2.5	Community Pharmacy	2	-	1
2.6	Pharmacotherapeutics-I	3	3	1
	Total Hours	**17**	**9**	**6 = 32**

Third Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
3.1	Pharmacology-II	3	3	1
3.2	Pharmaceutical Analysis	3	3	1
3.3	Pharmacotherapeutics-II	3	3	1
3.4	Pharmaceutical Jurisprudence	2	-	-
3.5	Medicinal Chemistry	3	3	1
3.6	Pharmaceutical Formulations	2	3	1
	Total hours	**16**	**15**	**5 = 36**

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Fourth Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical/ Hospital Posting	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
4.1	Pharmacotherapeutics-III	3	3	1
4.2	Hospital Pharmacy	2	3	1
4.3	Clinical Pharmacy	3	3	1
4.4	Biostatistics & Research Methodology	2	-	1
4.5	Biopharmaceutics & Pharmacokinetics	3	3	1
4.6	Clinical Toxicology	2	-	1
	Total hours	**15**	**12**	**6 = 33**

Fifth Year:

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Hospital posting*	No. of hours of Seminar
(1)	(2)	(3)	(4)	(5)
5.1	Clinical Research	3	-	1
5.2	Pharmacoepidemiology and Pharmacoeconomics	3	-	1
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	2	-	1
5.4	Clerkship *	-	-	1
5.5	Project work (Six Months)	-	20	-
	Total hours	**8**	**20**	**4 = 32**

* Attending ward rounds on daily basis.

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Sixth Year:

Internship or residency training including postings in speciality units. Student should independently provide the clinical pharmacy services to the allotted wards.

(i) Six months in General Medicine department. and

(ii) Two months each in three other speciality departments

8. Syllabus. – The syllabus for each subject of study in the said Tables shall be as specified in Appendix -A to these regulations.

9. Approval of the authority conducting the course of study. – (1) No person, institution, society or university shall start and conduct Pharm.D or Pharm.D. (Post Baccalaureate) programme without the prior approval of the Pharmacy Council of India.

(2) Any person or pharmacy college for the purpose of obtaining permission under sub-section (1) of section 12 of the Pharmacy Act, shall submit a scheme as prescribed by the Pharmacy Council of India.

(3) The scheme referred to in sub-regulation (2) above, shall be in such form and contain such particulars and be preferred in such manner and be accompanied with such fee as may be prescribed:

Provided that the Pharmacy Council of India shall not approve any institution under these regulations unless it provides adequate arrangements for teaching in regard to building, accommodation, labs., equipments, teaching staff, non-teaching staff, etc., as specified in Appendix-B to these regulations.

10. Examination. – (1) Every year there shall be an examination to examine the students.

(2) Each examination may be held twice every year. The first examination in a year shall be the annual examination and the second examination shall be supplementary examination.

(3) The examinations shall be of written and practical (including oral nature) carrying maximum marks for each part of a subject as indicated in Tables below :

TABLES

First Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
1.1	Human Anatomy and Physiology	70	30	100	70	30	100
1.2	Pharmaceutics	70	30	100	70	30	100
1.3	Medicinal Biochemistry	70	30	100	70	30	100
1.4	Pharmaceutical Organic Chemistry	70	30	100	70	30	100
1.5	Pharmaceutical Inorganic Chemistry	70	30	100	70	30	100
1.6	Remedial Mathematics/ Biology	70	30	100	70*	30*	100*
				600			600 @ 1200

* for Biology.

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Second Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
2.1	Pathophysiology	70	30	100	-	-	-
2.2	Pharmaceutical Microbiology	70	30	100	70	30	100
2.3	Pharmacognosy & Phytopharmaceuticals	70	30	100	70	30	100
2.4	Pharmacology-I	70	30	100	-	-	-
2.5	Community Pharmacy	70	30	100	-	-	-
2.6	Pharmacotherapeutics-I	70	30	100	70	30	100
				600			300 = 900

Third Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
3.1	Pharmacology-II	70	30	100	70	30	100
3.2	Pharmaceutical Analysis	70	30	100	70	30	100
3.3	Pharmacotherapeutics-II	70	30	100	70	30	100
3.4	Pharmaceutical Jurisprudence	70	30	100	-	-	-
3.5	Medicinal Chemistry	70	30	100	70	30	100
3.6	Pharmaceutical Formulations	70	30	100	70	30	100
				600			500 = 1100

Fourth Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
4.1	Pharmacotherapeutics-III	70	30	100	70	30	100
4.2	Hospital Pharmacy	70	30	100	70	30	100
4.3	Clinical Pharmacy	70	30	100	70	30	100
4.4	Biostatistics & Research Methodology	70	30	100	-	-	-
4.5	Biopharmaceutics & Pharmacokinetics	70	30	100	70	30	100
4.6	Clinical Toxicology	70	30	100	-	-	-
				600			400 = 1000

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Fifth Year examination :

S.No.	Name of Subject	Maximum marks for Theory			Maximum marks for Practicals		
		Examination	Sessional	Total	Examination	Sessional	Total
5.1	Clinical Research	70	30	100	-	-	-
5.2	Pharmacoepidemiology and Pharmacoeconomics	70	30	100	-	-	-
5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	70	30	100	-	-	-
5.4	Clerkship *	-	-	-	70	30	100
5.5	Project work (Six Months)	-	-	-	100**	-	100
				300			200 = 500

* Attending ward rounds on daily basis.

** 30 marks – viva-voce (oral)
70 marks – Thesis work

11. Eligibility for appearing Examination.— Only such students who produce certificate from the Head of the Institution in which he or she has undergone the Pharm.D. or as the case may be, the Pharm.D. (Post Baccalaureate) course, in proof of his or her having regularly and satisfactorily undergone the course of study by attending not less than 80% of the classes held both in theory and in practical separately in each subject shall be eligible for appearing at examination.

12. Mode of examinations.— (1) Theory examination shall be of three hours and practical examination shall be of four hours duration.

(2) A Student who fails in theory or practical examination of a subject shall re-appear both in theory and practical of the same subject.

(3) Practical examination shall also consist of a viva –voce (Oral) examination.

(4) Clerkship examination – Oral examination shall be conducted after the completion of clerkship of students. An external and an internal examiner will evaluate the student. Students may be asked to present the allotted medical cases followed by discussion. Students' capabilities in delivering clinical pharmacy services, pharmaceutical care planning and knowledge of therapeutics shall be assessed.

13. Award of sessional marks and maintenance of records.— (1) A regular record of both theory and practical class work and examinations conducted in an institution imparting training for Pharm.D. or as the case may be, Pharm.D. (Post Baccalaureate) course, shall be maintained for each student in the institution and 30 marks for each theory and 30 marks for each practical subject shall be allotted as sessional.

(2) There shall be at least two periodic sessional examinations during each academic year and the highest aggregate of any two performances shall form the basis of calculating sessional marks.

(3) The sessional marks in practicals shall be allotted on the following basis:-

(i) Actual performance in the sessional examination (20 marks);

(ii) Day to day assessment in the practical class work, promptness, viva-voce record maintenance, etc. (10 marks).

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14. Minimum marks for passing examination.— A student shall not be declared to have passed examination unless he or she secures at least 50% marks in each of the subjects separately in the theory examinations, including sessional marks and at least 50% marks in each of the practical examinations including sessional marks. The students securing 60% marks or above in aggregate in all subjects in a single attempt at the Pharm.D. or as the case may be, Pharm. D. (Post Baccalaureate) course examination shall be declared to have passed in first class. Students securing 75% marks or above in any subject or subjects shall be declared to have passed with distinction in the subject or those subjects provided he or she passes in all the subjects in a single attempt.

15. Eligibility for promotion to next year.— All students who have appeared for all the subjects and passed the first year annual examination are eligible for promotion to the second year and, so on. However, failure in more than two subjects shall debar him or her from promotion to the next year classes.

16. Internship.— (1) Internship is a phase of training wherein a student is expected to conduct actual practice of pharmacy and health care and acquires skills under the supervision so that he or she may become capable of functioning independently.

    (2) Every student has to undergo one year internship as per Appendix-C to these regulations.

17. Approval of examinations.— Examinations mentioned in regulations 10 to12 and 14 shall be held by the examining authority hereinafter referred to as the university, which shall be approved by the Pharmacy Council of India under sub-section (2) of section 12 of the Pharmacy Act, 1948. Such approval shall be granted only if the examining authority concerned fulfills the conditions as specified in Appendix–D to these regulations.

18. Certificate of passing examination.— Every student who has passed the examinations for the Pharm.D. (Doctor of Pharmacy) or Pharm.D. (Post Baccalaureate) (Doctor of Pharmacy) as the case may be, shall be granted a certificate by the examining authority.

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CHAPTER-III
Practical training

19. Hospital posting.— Every student shall be posted in constituent hospital for a period of not less than fifty hours to be covered in not less than 200 working days in each of second, third & fourth year course. Each student shall submit report duly certified by the preceptor and duly attested by the Head of the Department or Institution as prescribed. In the fifth year, every student shall spend half a day in the morning hours attending ward rounds on daily basis as a part of clerkship. Theory teaching may be scheduled in the afternoon.

20. Project work.— (1) To allow the student to develop data collection and reporting skills in the area of community, hospital and clinical pharmacy, a project work shall be carried out under the supervision of a teacher. The project topic must be approved by the Head of the Department or Head of the Institution. The same shall be announced to students within one month of commencement of the fifth year classes. Project work shall be presented in a written report and as a seminar at the end of the year. External and the internal examiners shall do the assessment of the project work.

(2) Project work shall comprise of objectives of the work, methodology, results, discussions and conclusions.

21. Objectives of project work.— The main objectives of the project work is to—

(i) show the evidence of having made accurate description of published work of others and of having recorded the findings in an impartial manner; and

(ii) develop the students in data collection, analysis and reporting and interpretation skills.

22. Methodology.— To complete the project work following methodology shall be adopted, namely:—

(i) students shall work in groups of not less than *two* and not more than *four* under an authorised teacher;

(ii) project topic shall be approved by the Head of the Department or Head of the Institution;

(iii) project work chosen shall be related to the pharmacy practice in community, hospital and clinical setup. It shall be patient and treatment (Medicine) oriented, like drug utilisation reviews, pharmacoepidemiology, pharmacovigilance or pharmacoeconomics;

(iv) project work shall be approved by the institutional ethics committee;

(v) student shall present at least three seminars, one in the beginning, one at middle and one at the end of the project work; and

(vi) two-page write-up of the project indicating title, objectives, methodology anticipated benefits and references shall be submitted to the Head of the Department or Head of the Institution.

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23. Reporting .— (1) Student working on the project shall submit jointly to the Head of the Department or Head of the Institution a project report of about 40-50 pages. Project report should include a certificate issued by the authorised teacher, Head of the Department as well as by the Head of the Institution

(2) Project report shall be computer typed in double space using Times Roman font on A4 paper. The title shall be in bold with font size 18, sub-tiles in bold with font size 14 and the text with font size 12. The cover page of the project report shall contain details about the name of the student and the name of the authorised teacher with font size 14.

(3) Submission of the project report shall be done at least one month prior to the commencement of annual or supplementary examination.

24. Evaluation.— The following methodology shall be adopted for evaluating the project work—

(i) Project work shall be evaluated by internal and external examiners.

(ii) Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of four students).

(iii) Three seminars presented by students shall be evaluated for twenty marks each and the average of best two shall be forwarded to the university with marks of other subjects.

(iv) Evaluation shall be done on the following items:

	Marks
a) Write up of the seminar	(7.5)
b) Presentation of work	(7.5)
c) Communication skills	(7.5)
d) Question and answer skills	(7.5)
Total	(30 marks)

(v) Final evaluation of project work shall be done on the following items:

	Marks
a) Write up of the seminar	(17.5)
b) Presentation of work	(17.5)
c) Communication skills	(17.5)
d) Question and answer skills	(17.5)
Total	(70 marks)

Explanation.— For the purposes of differentiation in the evaluation in case of topic being the same for the group of students, the same shall be done based on item numbers b, c and d mentioned above.

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APPENDIX-A

(See regulation 8)

PHARM.D. SYLLABUS

First Year

1.1 HUMAN ANATOMY & PHYSIOLOGY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope and Objectives:** This course is designed to impart a fundamental knowledge on the structure and functions of the human body. It also helps in understanding both homeostasis mechanisms and homeostatic imbalances of various body systems. Since a medicament, which is produced by pharmacist, is used to correct the deviations in human body, it enhances the understanding of how the drugs act on the various body systems in correcting the disease state of the organs.

2. **Upon completion of the course the student shall be able to:**
   a. describe the structure (gross and histology) and functions of various organs of the human body;
   b. describe the various homeostatic mechanisms and their imbalances of various systems;
   c. identify the various tissues and organs of the different systems of the human body;
   d. perform the hematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes;
   e. appreciate coordinated working pattern of different organs of each system; and
   f. appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body

3. **Course materials:**

   Text books
   a. Tortora Gerard J. and Nicholas, P. Principles of anatomy and physiology Publisher Harpercollins college New York.
   b. Wilson, K.J.W. Ross and Wilson's foundations of anatomy and physiology. Publisher: Churchill Livingstone, Edinburg.

   Reference books
   a. Guyton arthur, C. *Physiology of human body*. Publisher: Holtsaunders.
   b. Chatterjee,C.C. *Human physiology*. Volume 1&11. Publisher: medical allied agency, Calcutta.
   c. Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H.
   d. *Gray's anatomy*. Publisher:Churchill Livingstone, London.

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4. Lecture wise program :

Topics

1 Scope of anatomy and physiology, basic terminologies used in this subject (Description of the body as such planes and terminologies)

2 Structure of cell – its components and their functions.

3 Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics

4 a) Osseous system - structure, composition and functions of the Skeleton. (done in practical classes - 6hrs)
b) Classification of joints, Types of movements of joints and disorders of joints (Definitions only)

5 Haemopoetic System
a) Composition and functions of blood
b) Haemopoesis and disorders of blood components (definition of disorder)
c) Blood groups
d) Clotting factors and mechanism
e) Platelets and disorders of coagulation

6 Lymph
a) Lymph and lymphatic system, composition, formation and circulation.
b) Spleen: structure and functions, Disorders
c) Disorders of lymphatic system (definition only)

7 Cardiovascular system
a) Anatomy and functions of heart
b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation)
c) Electrocardiogram (ECG)
d) Cardiac cycle and heart sounds
e) Blood pressure – its maintenance and regulation
f) Definition of the following disorders
Hypertension, Hypotension, Arteriosclerosis, Atherosclerosis, Angina, Myocardial infarction, Congestive heart failure, Cardiac arrhythmias

8 Respiratory system
a) Anatomy of respiratory organs and functions
b) Mechanism / physiology of respiration and regulation of respiration
c) Transport of respiratory gases
d) Respiratory volumes and capacities, and Definition of: Hypoxia, Asphyxia, Dybarism, Oxygen therapy and resuscitation.

9 Digestive system
a) Anatomy and physiology of GIT
b) Anatomy and functions of accessory glands of GIT
c) Digestion and absorption
d) Disorders of GIT (definitions only)

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10 Nervous system
a) Definition and classification of nervous system
b) Anatomy, physiology and functional areas of cerebrum
c) Anatomy and physiology of cerebellum
d) Anatomy and physiology of mid brain
e) Thalamus, hypothalamus and Basal Ganglia
f) Spinal card: Structure & reflexes – mono-poly-planter
g) Cranial nerves – names and functions
h) ANS – Anatomy & functions of sympathetic & parasympathetic N.S.

11 Urinary system
a) Anatomy and physiology of urinary system
b) Formation of urine
c) Renin Angiotensin system – Juxtaglomerular apparatus - acid base Balance
d) Clearance tests and micturition

12 Endocrine system
a) Pituitary gland
b) Adrenal gland
c) Thyroid and Parathyroid glands
d) Pancreas and gonads

13 Reproductive system
a) Male and female reproductive system
b) Their hormones – Physiology of menstruation
c) Spermatogenesis & Oogenesis
d) Sex determination (genetic basis)
e) Pregnancy and maintenance and parturition
f) Contraceptive devices

14 Sense organs
a) Eye
b) Ear
c) Skin
d) Tongue & Nose

15 Skeletal muscles
a) Histology
b) Physiology of Muscle contraction
c) Physiological properties of skeletal muscle and their disorders (definitions)

16 Sports physiology
a) Muscles in exercise, Effect of athletic training on muscles and muscle performance,
b) Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,
c) Drugs and athletics

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1.1 HUMAN ANATOMY & PHYSIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

General Requirements: Dissection box, Laboratory Napkin, muslin cloth, record, Observation book(100pages), Stationary items, Blood lancet.

Course materials:

Text books

Goyal, R. K, Natvar M.P, and Shah S.A, Practical anatomy, physiology and biochemistry, latest edition, Publisher: B.S Shah Prakashan, Ahmedabad.

Reference books

Ranade VG, Text book of practical physiology, Latest edition, Publisher: PVG, Pune
Anderson Experimental Physiology, Latest edition, Publisher: NA

List of Experiments:

1. Study of tissues of human body
   (a) Epithelial tissue.
   (b) Muscular tissue.
2. Study of tissues of human body
   (a) Connective tissue.
   (b) Nervous tissue.
3. Study of appliances used in hematological experiments.
4. Determination of W.B.C. count of blood.
5. Determination of R.B.C. count of blood.
6. Determination of differential count of blood.
7. Determination of
   (a) Erythrocyte Sedimentation Rate.
   (b) Hemoglobin content of Blood.
   (c) Bleeding time & Clotting time.
8. Determination of
   (a) Blood Pressure.
   (b) Blood group.
9. Study of various systems with the help of charts, models & specimens
   (a) Skeleton system part I-axial skeleton.
   (b) Skeleton system part II- appendicular skeleton.
   (c) Cardiovascular system.
   (d) Respiratory system.

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(e) Digestive system.
(f) Urinary system.
(g) Nervous system.
(h) Special senses.
(i) Reproductive system.

10. Study of different family planning appliances.

11. To perform pregnancy diagnosis test.

12. Study of appliances used in experimental physiology.

13. To record simple muscle curve using gastroenemius sciatic nerve preparation.

14. To record simple summation curve using gastroenemius sciatic nerve preparation.

15. To record simple effect of temperature using gastroenemius sciatic nerve preparation.

16. To record simple effect of load & after load using gastroenemius sciatic nerve preparation.

17. To record simple fatigue curve using gastroenemius sciatic nerve preparation.

Scheme of Practical Examination:

	Sessionals	**Annual**
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

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1.2 PHARMACEUTICS (THEORY)

Theory : 2 Hrs. /Week

1. **Scope and objectives:** This course is designed to impart a fundamental knowledge on the art and science of formulating different dosage forms. It prepares the students for most basics of the applied field of pharmacy.

2. **Upon the completion of the course the student should be able to:**
   a. know the formulation aspects of different dosage forms;
   b. do different pharmaceutical caluculation involved in formulation;
   c. formulate different types of dosage forms; and
   d. appreciate the importance of good formulation for effectiveness.

3. **Course materials:**

   Text books
   a. Cooper and Gunns Dispensing for pharmacy students.
   b. A text book Professional Pharmacy by N.K.Jain and S.N.Sharma.

   Reference books
   a. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
   b. Remington's Pharmaceutical Sciences.
   c. Register of General Pharmacy by Cooper and Gunn.
   d. General Pharmacy by M.L.Schroff.

4. **Lecture wise programme:**

   Topics

   1 a. Introduction to dosage forms - classification and definitions
   b. Prescription: definition, parts and handling
   c. Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses.
   2 Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.
   3 Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.
   4 Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.
   5 Powders and Granules: Classification advantages and disadvantages, Preparation of simple, compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules.
   6 Monophasic Dosage forms: Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavours with examples. Study of Monophasic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.

7 Biphasic dosage forms: Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.
8 Suppositories and pessaries: Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.
9 Galenicals: Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.
10 Pharmaceutical calculations.
11 Surgical aids: Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages.
12 Incompatibilities: Introduction, classification and methods to overcome the incompatibilities.

1.2 PHARMACEUTICS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

1. **Syrups**
   a. Simple Syrup I.P
   b. Syrup of Ephedrine Hcl NF
   c. Syrup Vasaka IP
   d. Syrup of ferrous-Phosphate IP
   e. Orange Syrup
2. **Elixir**
   a. Piperizine citrate elixir BP
   b. Cascara elixir BPC
   c. Paracetamol elixir BPC
3. **Linctus**
   a. Simple Linctus BPC
   b. Pediatric simple Linctus BPC
4. **Solutions**
   a. Solution of cresol with soap IP
   b. Strong solution of ferric chloride BPC
   c. Aqueous Iodine Solution IP
   d. Strong solution of Iodine IP
   e. Strong solution of ammonium acetate IP

5. **Liniments**
   a. Liniment of turpentine IP*
   b. Liniment of camphor IP
6. **Suspensions***
   a. Calamine lotion
   b. Magnesium Hydroxide mixture BP
7. **Emulsions***
   a. Cod liver oil emulsion
   b. Liquid paraffin emulsion
8. **Powders***
   a. Eutectic powder
   b. Explosive powder
   c. Dusting powder
   d. Insufflations
9. **Suppositories***
   a. Boric acid suppositories
   b. Chloral suppositories
10. **Incompatibilities**
    a. Mixtures with Physical
    b. Chemical & Therapeutic incompatibilities

* colourless bottles required for dispensing * Paper envelope (white), butter paper and white paper required for dispensing.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

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1.3 MEDICINAL BIOCHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** Applied biochemistry deals with complete understanding of the molecular level of the chemical process associated with living cells.Clinical chemistry deals with the study of chemical aspects of human life in health and illness and the application of chemical laboratory methods to diagnosis, control of treatment, and prevention of diseases.

2. **Objectives of the Subject** (Know, do, appreciate) :
   The objective of the present course is providing biochemical facts and the principles to the students of pharmacy. Upon completion of the subject student shall be able to –
   a. understand the catalytic activity of enzymes and importance of isoenzymes, in diagnosis of diseases;
   b. know the metabolic process of biomolecules in health and illness (metabolic disorders);
   c. understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism:
   d. know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and
   e. do the qualitative analysis and determination of biomolecules in the body fluids.

   Text books (Theory)
   a. Harpers review of biochemistry - Martin
   b. Text book of biochemistry – D.Satyanarayana
   c. Text book of clinical chemistry- Alex kaplan &Laverve L.Szabo

   Reference books (Theory)
   a. Principles of biochemistry -- Lehninger
   b. Text book of biochemistry -- Ramarao
   c. Practical Biochemistry-David T.Plummer.
   d. Practical Biochemistry-Pattabhiraman.

3. **Lecture wise programme:**

   Topics

   1 **Introduction to biochemistry:** Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance.
   2 **Enzymes**: Definition; Nomenclature; IUB classification; Factor affecting enzyme activity; Enzyme action; enzyme inhibition. Isoenzymes and their therapeutic and diagnostic applications; Coenzymes and their biochemical role and deficiency diseases.
   3 **Carbohydrate metabolism**: Glycolysis, Citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, gluconeogenesis, glycogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose, Galactose tolerance test and their significance; hormonal regulation of carbohydrate metabolism.

4 **Lipid metabolism:** Oxidation of saturated (β-oxidation); Ketogenesis and ketolysis; biosynthesis of fatty acids, lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atheroslerosis, fatty liver, hypercholesterolmiea).

5 **Biological oxidation:** Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture; regulation and inhibition); Uncouplers of ETC; Oxidative phosphorylation;

6 **Protein and amino acid metabolism:** protein turn over; nitrogen balance; Catabolism of Amino acids (Transamination, deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphoria, jaundice. Metabolic disorder of Amino acids.

7 **Nucleic acid metabolism:** Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; mutation ,and repair mechanism; DNA replication (semiconservative /onion peel models) and DNA repair mechanism.

8 **Introduction to clinical chemistry: Cell**; composition; malfunction; Roll of the clinical chemistry laboratory.

9 **The kidney function tests:** Role of kidney; Laboratory tests for normal function includes-

a) Urine analysis (macroscopic and physical examination, quantitative and semiquantitative tests.)
b) Test for NPN constituents. (Creatinine /urea clearance, determination of blood and urine creatinine, urea and uric acid)
c) Urine concentration test
d) Urinary tract calculi. (stones)

10 **Liver function tests:** Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation.

a) Test for hepatic dysfunction-Bile pigments metabolism.
b) Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.
c) Dye tests of excretory function.
d) Tests based upon abnormalities of serum proteins.

Selected enzyme tests.

11 **Lipid profile tests:** Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.

12 **Immunochemical techniques** for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases.

Radio immuno assay (RIA) and Enzyme Linked Immuno Sorbent Assay (ELISA)

13 **Electrolytes:** Body water, compartments, water balance, and electrolyte distrubution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids.

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1.3 MEDICINAL BIOCHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

Title of the Experiment:

1 Qualitative analysis of normal constituents of urine.*
2 Qualitative analysis of abnormal constituents of urine.*
3 Quantitative estimation of urine sugar by Benedict's reagent method.**
4 Quantitative estimation of urine chlorides by Volhard's method.**
5 Quantitative estimation of urine creatinine by Jaffe's method.**
6 Quantitative estimation of urine calcium by precipitation method.**
7 Quantitative estimation of serum cholesterol by Libermann Burchard's method.**
8 Preparation of Folin Wu filtrate from blood.*
9 Quantitative estimation of blood creatinine.**
10 Quantitative estimation of blood sugar Folin-Wu tube method.**
11 Estimation of SGOT in serum.**
12 Estimation of SGPT in serum.**
13 Estimation of Urea in Serum.**
14 Estimation of Proteins in Serum.**
15 Determination of serum bilirubin**
16 Determination of Glucose by means of Glucoseoxidase.**
17 Enzymatic hydrolysis of Glycogen/Starch by Amylases.**
18 Study of factors affecting Enzyme activity. (pH & Temp.)**
19 Preparation of standard buffer solutions and its pH measurements (any two)*
20 Experiment on lipid profile tests**
21 Determination of sodium,calcium and potassium in serum.**

** indicate major experiments & * indicate minor experiments

Assignments:

Format of the assignment

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

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1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope and objectives**: This course is designed to impart a very good knowledge about
   a. IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds;
   b. Some important physical properties of organic compounds;
   c. Free radical/ nucleophyllic [alkyl/ acyl/ aryl] /electrophyllic substitution, free radical/ nucleophyllic / electrophyllic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds;
   d. Some named organic reactions with mechanisms; and
   e. Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

2. **Course materials:**

   Text books
   a. T.R.Morrison and R. Boyd - Organic chemistry,
   b. Bentley and Driver-Text book of Pharmaceutical chemistry
   c. I.L.Finer- Organic chemistry, the fundamentals of chemistry

   Reference books
   a. Organic chemistry – J.M.Cram and D.J.Cram
   b. Organic chemistry- Brown
   c. Advanced organic chemistry- Jerry March, Wiley
   d. Organic chemistry- Cram and Hammered, Pine Hendrickson

3. **Lecture wise programme :**

   Topics

   1 Structures and Physical properties:
      a. Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P, Solubility, non ionic solutes and ionic solutes, protic and aprotic Solvents, ion pairs,
      b. Acids and bases, Lowry bronsted and Lewis theories
      c. Isomerism
   2 Nomenclature of organic compound belonging to the following classes Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines, Phenols, Alkyl Halides, Carboxylic Acid, Esters, Acid Chlorides And Cycloalkanes.
   3 Free radicals chain reactions of alkane : Mechanism, relative reactivity and stability
   4 Alicyclic compounds : Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.
   5 Nuclophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN_2 reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN1 reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN1 reaction, Ion dipole bonds, SN2 versus SN1 solvolyses, nucleophilic assistance by the solvents.

6 Dehydro halogenation of alkyl halides: 1,2 elimination, kinetics, E2 and E1 mechanism, elimination via carbocation, evidence for E2 mechanism, absence of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity. E2 versus E1, elimination versus substitution, dehydration of alcohol. ease of dehydration, acid catalysis, reversibility, orientation.

7 Electrophillic and free radicals addition: Reactions at carbon-carbon, double bond, electrophile, hydrogenation, heat of hydrogenation and stability of alkenes, markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophillic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, halohydin formation, mechanism of free radicals additon, mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition, additions of carbene to alkene, cyclo addition reactions.

8 Carbon-carbon double bond as substituents: Free radical halogenations of alkenes, comparision of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.

9 Theory of resonance: Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl radicals, hyper conjugation, allyl cation as a resonance hybrid, nucleophyllic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilisation of allyl cation, hyper conjugation, nucleophilic substitution in allylic substrate, SN2 nucleophilic substituion in vinylic substrate, vinylic cation, stability of conjugated dienes, resonance in alkenes, hyper conjugation, ease of formation of conjugated dienes, orientation of elimination, electrophilic addition to conjugated dienes, 1,4- addition, 1,2-versus 1,4-addition, rate versus equilibrium, orientation and reactivity of free radical addition to conjugated dienes.

10 Elecrophilic aromatic substitution: Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration, sulphonation, halogenation, friedel craft alkylation, friedel craft acylation, reactivity and orientation, activating and deactivating O,P,M directing groups, electron release via resonance, effect of halogen on electrophilic aromatic substitution in alkyl benzene, side chain halogination of alkyl benzene, resonance stabilization of benzyl radical.

11 Nucleophilic addition reaction: Mechanism, ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, effect of substituent on acidity, nucleophilic acyl substitution reaction, conversion of acid to acid chloride, esters, amide and anhydride. Role of caboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution.

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12 Mechanism of aldol condensation, claisen condensation, cannizzaro reaction, crossed aldol condensation, crossed cannizzaro reaction, benzoin condensation, perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition.

13 Hoffman rearrangement: Migration to electron deficient nitrogen, Sandmeyer's reaction, basicity of amines, diazotisation and coupling, acidity of phenols, Williamson synthesis, Fries rearrangement, Kolbe reaction, Reimer tieman's reactions.

14 Nucleophilic aromatic substitution: Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.

15 Oxidation reduction reaction.

16 Study of the following official compounds- preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea, Ethylene diamine dihyrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin, methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl pthalate, sodium lauryl sulphate, saccharin sodium, mephensin.

1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

I. Introduction to the various laboratory techniques through demonstration involving synthesis of the following compounds (at least 8 compounds to be synthesised):

1. Acetanilde / aspirin (Acetylation)
2. Benzanilide / Phenyl benzoate (Benzoylation)
3. P-bromo acetanilide / 2,4,6 – tribromo aniline (Bromination)
4. Dibenzylidene acetone (Condensation)
5. 1-Phenylazo-2-napthol (Diazotisation and coupling)
6. Benzoic acid / salicylic acid (Hydrolysis of ester)
7. M-dinitro benzene (Nitration)
8. 9, 10 – Antharaquinone (Oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde
9. M-phenylene diamine (Reduction of M-dinitrobenzene) / Aniline from nitrobenzene
10. Benzophenone oxime
11. Nitration of salicylic acid
12. Preparation of picric acid
13. Preparation of O-chlorobenzoic acid from O-chlorotolune
14. Preparation of cyclohexanone from cyclohexanol

II. Identification of organic compounds belonging to the following classes by :

Systematic qualitative organic analysis including preparation of derivatives Phenols, amides, carbohydrates, amines, carboxylic acids, aldehyde and ketones, Alcohols, esters. hydrocarbons, anilides, nitrocompounds.

III. Introduction to the use of stereo models:

Methane, Ethane, Ethylene, Acetylene, Cis alkene, Trans alkene, inversion of configuration.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

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1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope and objectives:** This course mainly deals with fundamentals of Analytical chemistry and also the study of inorganic pharmaceuticals regarding their monographs and also the course deals with basic knowledge of analysis of various pharmaceuticals.

2. **Upon completion of the course student shall be able to:**
   a. under stand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceuticals;
   b. know the analysis of the inorganic pharmaceuticals their applications; and
   c. appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.

3. **Course materials:**

   Text books
   a. A text book Inorganic medicinal chemistry by Surendra N. Pandeya
   b. A. H. Beckett and J. B. Stanlake's Practical Pharmaceutical chemistry Vol-I & Vol-II
   c. Inorganic Pharmaceutical Chemistry III-Edition P.Gundu Rao

   Reference books
   a. Inorganic Pharmaceutical Chemistry by Anand & Chetwal
   b. Pharmaceutical Inorganic chemistry by Dr.B.G.Nagavi
   c. Analytical chemistry principles by John H. Kennedy
   d. I.P.1985 and 1996, Govt. of India, Ministry of health

4. **Lecture wise programme:**

   Topics
   1 Errors
   2 Volumetric analysis
   3 Acid-base titrations
   4 Redox titrations
   5 Non aqueous titrations
   6 Precipitation titrations
   7 Complexometric titrations
   8 Theory of indicators
   9 Gravimetry
   10 Limit tests
   11 Medicinal gases
   12 Acidifiers
   13 Antacids
   14 Cathartics
   15 Electrolyte replenishers

16 Essential Trace elements
17 Antimicrobials
18 Pharmaceutical aids
19 Dental Products
20 Miscellaneous compounds
21 Radio Pharmaceuticals

1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

1. **Limit test (6 exercises)**
   a. Limit test for chlorides
   b. Limit test for sulphates
   c. Limit test for iron
   d. Limit test for heavy metals
   e. Limit test for arsenic
   f. Modified limit tests for chlorides and sulphates

2. **Assays (10 exercises)**
   a. Ammonium chloride- Acid-base titration
   b. Ferrous sulphate- Cerimetry
   c. Copper sulpahte- Iodometry
   d. Calcilugluconate- Complexometry
   e. Hydrogen peroxide – Permanganometry
   f. Sodium benzoate – Nonaqueous titration
   g. Sodium chloride – Modified volhard's method
   h. Assay of KI – KIO_3 titration
   i. Gravimetric estimation of barium as barium sulphate
   j. Sodium antimony gluconate or antimony potassium tartarate

3. **Estimation of mixture (Any two exercises)**
   a. Sodium hydroxide and sodium carbonate
   b. Boric acid and Borax
   c. Oxalic acid and sodium oxalate

4. **Test for identity (Any three exercises)**
   a. Sodium bicorbonate
   b. Barium sulphate
   c. Ferrous sulphate
   d. Potassium chloride

5. **Test for purity (Any two exercises)**
   a. Swelling power in Bentonite
   b. Acid neutralising capacity in aluminium hydroxide gel
   c. Ammonium salts in potash alum
   d. Adsorption power heavy Kaolin
   e. Presence of Iodates in KI

6. **Preparations (Any two exercises)**
   a. Boric acids
   b. Potash alum
   c. Calcium lactate
   d. Magnesium suphate

Scheme of Practical Examination :

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment1 &2	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

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1.6 REMEDIAL MATHEMATICS/BIOLOGY (THEORY)

Theory : 3 Hrs. /Week

REMEDIAL MATHEMATICS :

1. **Scope and objectives**: This is an introductory course in mathematics. This subjects deals with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, laplace transform.

2. **Upon completion of the course the student shall be able to : –**
   a. Know Trignometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications;
   b. solve the problems of different types by applying theory; and
   c. appreciate the important applications of mathematics in pharmacy.

3. **Course materials:**

   Text books
   a. Differential calculus By Shantinarayan
   b. Text book of Mathematics for second year pre-university by Prof.B.M.Sreenivas

   Reference books
   a. Integral calculus By Shanthinarayan
   b. Engineering mathematics By B.S.Grewal
   c. Trigonometry Part-I By S.L.Loney

4. **Lecture wise programme :**

   Topics

   1 **Algebra :** Determinants, Matrices
   2 **Trigonometry :** Sides and angles of a triangle, solution of triangles
   3 **Analytical Geometry :**Points, Straight line, circle, parabola
   4 **Differential calculus:** Limit of a function, Differential calculus, Differentiation of a sum, Product, Quotient Composite, Parametric, exponential, trigonometric and Logarithmic function. Successive differentiation, Leibnitz's theorem, Partial differentiation, Euler's theorem on homogeneous functions of two variables
   5 **Integral Calculus:** Definite integrals, integration by substitution and by parts, Properties of definite integrals.
   6 **Differential equations:** Definition, order, degree, variable separable, homogeneous, Linear, heterogeneous, linear, differential equation with constant coefficient, simultaneous linear equation of second order.
   7 **Laplace transform:** Definition, Laplace transform of elementary functions, Properties of linearity and shifting.

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BIOLOGY :

1. **Scope and objectives**: This is an introductory course in Biology, which gives detailed study of natural sources such as plant and animal origin. This subject has been introduces to the pharmacy course in order to make the student aware of various naturally occurring drugs and its history, sources, classification, distribution and the characters of the plants and animals. This subject gives basic foundation to Pharmacognosy.

2. **Course materials:**

Text books

a. Text book of Biology by S.B.Gokhale
b. A Text book of Biology by Dr.Thulajappa and Dr. Seetaram.

Reference books

a. A Text book of Biology by B.V.Sreenivasa Naidu
b. A Text book of Biology by Naidu and Murthy
c. Botany for Degree students By A.C.Dutta.
d. Outlines of Zoology by M.Ekambaranatha ayyer and T.N.Ananthakrishnan.
e. A manual for pharmaceutical biology practical by S.B.Gokhale and C.K.Kokate.

3. **Lecture wise programme :**

Topic

PART – A

01 Introduction
02 General organization of plants and its inclusions
03 Plant tissues
04 Plant kingdom and its classification
05 Morphology of plants
06 Root, Stem, Leaf and Its modifications
07 Inflorescence and Pollination of flowers
08 Morphology of fruits and seeds
09 Plant physiology
10 Taxonomy of Leguminosae, umbelliferae, Solanaceae, Lilliaceae, Zinziberaceae, Rubiaceae
11 Study of Fungi, Yeast, Penicillin and Bacteria

PART-B

01 Study of Animal cell
02 Study animal tissues
03 Detailed study of frog
04 Study of Pisces, Raptiles, Aves
05 Genearal organization of mammals
06 Study of poisonous animals

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1.6 BIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

Title:

1. Introduction of biology experiments
2. Study of cell wall constituents and cell inclusions
3. Study of Stem modifications
4. Study of Root modifications
5. Study of Leaf modifications
6. Identification of Fruits and seeds
7. Preparation of Permanent slides
8. T.S. of Senna, Cassia, Ephedra, Podophyllum.
9. Simple plant physiological experiments
10. Identification of animals
11. Detailed study of Frog
12. Computer based tutorials

Scheme of Practical Examination :

	Sessionals	**Annual**
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.

Second year

2.1 PATHOPHYSIOLOGY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic Pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge of its application in other subject of pharmacy.

2. **Objectives of the Subject :** Upon completion of the subject student shall be able to –
   a. describe the etiology and pathogenesis of the selected disease states;
   b. name the signs and symptoms of the diseases; and
   c. mention the complications of the diseases.

   Text books (Theory)
   a. Pathologic basis of disease by- Cotran, Kumar, Robbins
   b. Text book of Pathology- Harsh Mohan
   c. Text book of Pathology- Y.M. Bhinde

   Reference books (Theory)
   a. Clinical Pharmacy and Therapeutics; Second edition; Roger Walker; Churchill Livingstone publication

3. **Detailed syllabus and lecture wise schedule :**

   Chapter

   1 **Basic principles of cell injury and Adaptation**
   a) Causes, Pathogenesis and morphology of cell injury
   b) Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen infiltration and glycogen infiltration and glycogen storage diseases

   2 **Inflammation**
   a) Pathogenesis of acute inflammation, Chemical mediators in inflammation, Types of chronic inflammation
   b) Repairs of wounds in the skin, factors influencing healing of wounds

   3 **Diseases of Immunity**
   a) Introduction to Tand B cells
   b) MHC proteins or transplantation antigens
   c) Immune tolerance
   - Hypersensitivity
     Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs
   - Autoimmunity
     Criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft.
   - Acquired immune deficiency syndrome (AIDS)

- Amylodosis

4 **Cancer:** differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classification of tumors, general biology of tumors, spread of malignant tumors, etiology and pathogenesis of cancer.

5 Types of shock. mechanisms, stages and management

6 Biological effects of radiation

7 Environmental and nutritional diseases
   i) Air pollution and smoking- SO2,NO, NO2, and CO
   ii) Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.

8 Pathophysiology of common diseases
   a. Parkinsonism
   b. Schizophrenia
   c. Depression and mania
   d. Hypertension,
   e. Stroke (ischaemic and hemorrhage)
   f. Angina, CCF, Atherosclerosis, Myocardial infarction
   g. Diabetes Mellitus
   h. Peptic ulcer and inflammatory bowel diseases
   i. Cirrhosis and Alcoholic liver diseases
   j. Acute and chronic renal failure
   k. Asthma and chronic obstructive airway diseases

9 Infectious diseases :
   Sexually transmitted diseases (HIV,Syphilis,Gonorrhea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic), Hepatitis- infective hepatitis.

4. Assignments :

Title of the Experiment

1 Chemical Mediators of inflammation
2 Drug Hypersensitivity
3 Cigarette smoking & its ill effects
4 Biological Effects of Radiation
5 Etiology and hazards of obesity
6 Complications of diabetes
7 Diagnosis of cancer
8 Disorders of vitamins
9 Methods in Pathology-Laboratory values of clinical significance
10 Pathophysiology of Dengue Hemorrhagic Fever (DHF)

Format of the assignment

1 Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy.
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

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2.2 PHARMACEUTICAL MICROBIOLOGY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** Microbiology has always been an essential component of pharmacy curriculum. This is because of the relevance of microbiology to pharmaceutical sciences and more specifically to pharmaceutical industry. Pharmaceutical biotechnology is the logical extension of pharmaceutical microbiology, which is expected to change the complete drug product scenario in the future.
   This course deals with the various aspects of microorganisms, its classification, morphology, laboratory cultivation identification and maintenance. Its also discusses with sterilization of pharmaceutical products, equipment, media etc. The course further discusses the immunological preparations, diseases, its transmission, diagnosis, control and immunological tests.

2. **Objectives of the Subject :**
   Upon completion of the subject student shall be able to –
   a. know the anatomy, identification, growth factors and sterilization of microorganisms;
   b. know the mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect;
   c. do estimation of RNA and DNA and there by identifying the source;
   d. do cultivation and identification of the microorganisms in the laboratory;
   e. do identification of diseases by performing the diagnostic tests; and
   f. appreciate the behavior of motility and behavioral characteristics of microorganisms.

Text books (Theory)

a. Vanitha Kale and Kishor Bhusari " Applied Microbiology " Himalaya Publishing house Mumbai.
b. Mary Louis Turgeon " Immunology and Serology in Laboratory Medicines" 2nd edition, 1996 Mosby- Year book inc St. Louis Missouri 63146.
c. Harsh Mohan, " Text book of Pathology" 3rd edition, 1998, B-3 Ansari road Darya ganj N. Delhi.

Reference books (Theory)

a. Prescot L.M., Jarley G.P Klein D.A "Microbiology" 2nd- edition Mc Graw Hill Company Inc
b. Rawlins E.A."Bentley's Text Book of Pharmaceutics" B ailliere Tindals 24-28 London 1988
c. Forbisher " Fundamentals of Microbiology" Philidelphia W.B. Saunders.
d. Prescott L.M. Jarley G.P., Klein.D.A. " Microbiology."2nd edition WMC Brown Publishers, Oxford. 1993
e. War Roitt, Jonathan Brostoff, David male, " Immunology"3rd edition 1996, Mosby-year book Europe Ltd, London.
f. Pharmacopoeia of India, Govt of India, 1996.

3. Detailed syllabus and lecture wise schedule :

Title of the topic

1 Introduction to the science of microbiology. Major divisions of microbial world and Relationship among them.

2 Different methods of classification of microbes and study of Bacteria, Fungi, virus, Rickettsiae, Spirochetes.

3 Nutritional requirements, growth and cultivation of bacteria and virus. Study of different important media required for the growth of aerobic and anaerobic bacteria & fungi. Differential media, enriched media and selective media, maintenance of lab cultures.

4 Different methods used in isolation and identification of bacteria with emphasis to different staining techniques and biochemical reactions. Counting of bacteria -Total and Viable counting techniques.

5 Detailed study of different methods of sterilization including their merits and demerits. Sterilization methods for all pharmaceutical products. Detailed study of sterility testing of different pharmaceutical preparations . Brief information on Validation.

6 Disinfectants- Study of disinfectants, antiseptics, fungicidal and virucidal agents factors affecting their activation and mechanism of action. Evaluation of bactericidal, bacteristatic, , virucidal activities, evaluation of preservatives in pharmaceutical preparations.

7 Immunology- Immunity, Definition, Classification, General principles of natural immunity, Phagocytosis, acquired immunity(active and passive) . Antigens, chemical nature of antigens structure and formation of Antibodies, Antigen-Antibody reactions. Bacterial exotoxins and endotoxins. Significance of toxoids in active immunity, Immunization programme, and importance of booster dose.

8 Diagnostic tests : Schick's Test, Elisa test, Western Blot test, Southern Blot PCR Widal, QBC, Mantaux Peripheral smear. Study of malarial parasite.

9 Microbial culture sensitivity Testing: Interpretation of results Principles and methods of different microbiological assays, microbiological assay of Penicillin, Streptomycin and vitamin B_2 and B_{12}. Standardisation of vaccines and sera.

10 Study of infectious diseases: Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhea and HIV.

2.2 PHARMACEUTICAL MICROBIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

Title of the Experiment:

1 Study of apparatus used in experimental microbiology*.

2 Sterilisation of glass ware's. Preparation of media and sterilisation.*

3 Staining techniques – Simple staining ; Gram's staining ; Negative staining**

4 Study of motility characters*.

5 Enumeration of micro-organisms (Total and Viable)*

6 Study of the methods of isolation of pure culture.*

7 Bio chemical testing for the identification of micro*-organisms.

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8 Cultural sensitivity testing for some micro-organisms.*
9 Sterility testing for powders and liquids.*
10 Determination of minimum inhibitory concentration.*
11 Microbiological assay of antibiotics by cup plate method.*
12 Microbiological assay of vitamins by Turbidometric method**
13 Determination of RWC.**
14 Diagnostic tests for some common diseases, Widal, malarial parasite.**

* Indicate minor experiment & ** indicate major experiment

Assignments:

1 Visit to some pathological laboratories & study the activities and equipment/instruments used and reporting the same.
2. Visit to milk dairies (Pasturization) and microbial laboratories(other sterization methods) & study the activities and equipment/instruments used and reporting the same.
3. Library assignments
   a. Report of recent microbial techniques developed in diagnosing some common diseases.
   b. Latest advancement developed in identifying, cultivating & handling of microorganisms.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

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2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (THEORY)

Theory : 3 Hrs. /Week

1. **Scope and objectives:** This subject has been introduced for the pharmacy course in order to make the student aware of medicinal uses of various naturally occurring drugs its history, sources, distribution, method of cultivation, active constituents, medicinal uses, identification tests, preservation methods, substitutes and adulterants.

2. **Upon completion of the course student shall be able to:**
   a. under stand the basic principles of cultivation, collection and storage of crude drugs;
   b. know the source, active constituents and uses of crude drugs; and
   c. appreciate the applications of primary and secondary metabolites of the plant.

3. **Course materials:**

   Text books
   a. Pharmacognosy by G.E. Trease & W.C.Evans.
   b. Pharmacognosy by C.K.Kokate,Gokhale & A.C.Purohit.

   Reference books
   a. Pharmacognosy by Brady &Tyler.E.
   b. Pharmacognosy by T.E.Wallis.
   c. Pharmacognosy by C.S. Shah & Qadery.
   d. Pharmacognosy by M.A. Iyengar.

4. **Lecture wise programme:**

   Topics

1	Introduction.
2	Definition, history and scope of Pharmacognosy.
3	Classification of crude drugs.
4	Cultivation, collection, processing and storage of crude drugs.
5	Detailed method of cultivation of crude drugs.
6	Study of cell wall constituents and cell inclusions.
7	Microscopical and powder Microscopical study of crude drugs.
8	Study of natural pesticides.
9	Detailed study of various cell constituents.
10	Carbohydrates and related products.
11	Detailed study carbohydrates containing drugs.(11 drugs)
12	Definition sources, method extraction, chemistry and method of analysis of lipids.
13	Detailed study of oils.
14	Definition, classification, chemistry and method of analysis of protein.
15	Study of plants fibers used in surgical dressings and related products.
16	Different methods of adulteration of crude drugs.

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2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (PRACTICAL)

Practical : 3 Hrs./Week

General Requirements: Laboratory Napkin, Observation Book 150 pages Zero brush, Needle, Blade, Match box.

List of experiments:

1 Introduction of Pharmacognosy laboratory and experiments.
2 Study of cell wall constituents and cell inclusions.
3 Macro, powder and microscopic study of Datura.
4 Macro, powder and microscopic study of Senna.
5 Macro, powder and microscopic study of Cassia.cinnamon.
6 Macro, powder and microscopic study of Cinchona.
7 Macro, powder and microscopic study of Ephedra.
8 Macro, powder and microscopic study of Quassia.
9 Macro, powder and microscopic study of Clove
10 Macro, powder and microscopic study of Fennel.
11 Macro, powder and microscopic study of Coriander.
12 Macro, powder and microscopic study of Isapgol.
13 Macro, powder and microscopic study of Nux vomica.
14 Macro, powder and microscopic study of Rauwolfia.
15 Macro, powder and microscopic study of Liquorice.
16 Macro, powder and microscopic study of Ginger.
17 Macro, powder and microscopic study of Podophyllum.
18 Determination of Iodine value.
19 Determination of Saponification value and unsaponifiable matter.
20 Determination of ester value.
21 Determination of Acid value.
22 Chemical tests for Acacia.
23 Chemical tests for Tragacanth.
24 Chemical tests for Agar.
25 Chemical tests for Starch.
26 Chemical tests for Lipids.(castor oil,sesame oil, shark liver oil,bees wax)
27 Chemical tests for Gelatin.

Scheme of Practical Examination:

	Sessionals	**Annual**
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.

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2.4 PHARMACOLOGY – I (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, apart from general pharmacology, drugs acting on autonomic nervous system, cardiovascular system, central nervous system, blood and blood forming agents and renal system will be taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.

2. **Objectives of the Subject :** Upon completion of the subject student shall be able to (Know, do, appreciate) –
   a. understand the pharmacological aspects of drugs falling under the above mentioned chapters;
   b. handle and carry out the animal experiments;
   c. appreciate the importance of pharmacology subject as a basis of therapeutics; and
   d. correlate and apply the knowledge therapeutically.

Text books (Theory) (Author, Title, Edition, Publication Place, Publisher, Year of Publication)

a. Tripathi, K. D. Essentials of medical pharmacology. 4th Ed, 1999. Publisher: Jaypee, Delhi.
b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
c. Rang, H.P. & Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)(Author, Title, Edition, Publication Place, Publisher, Publication Year)

a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th Ed, 1996. Publisher Mc Graw Hill, Pergamon press.
b. Craig, C.R.&Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown.Co
c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
d. Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher: Prentice Hall, London.

Text books (Practical) :
Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical)

a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.

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b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

3. Detailed syllabus and lecture wise schedule :

Title of the topic

1. **General Pharmacology**
   a) Introduction, definitions and scope of pharmacology
   b) Routes of administration of drugs
   c) Pharmacokinetics (absorption, distribution, metabolism and excretion)
   d) Pharmacodynamics
   e) Factors modifying drug effects
   f) Drug toxicity - Acute, sub- acute and chronic toxicity.
   g) Pre-clinical evaluations
   h) Drug interactions

   Note: The term Pharmacology used here refers to the classification, mechanism of action, pharmacokinetics, pharmacodynamics, adverse effects, contraindications, Therapeutic uses, interactions and dose and route of administration.

2. **Pharmacology of drugs acting on ANS**
   a) Adrenergic and antiadrenergic drugs
   b) Cholinergic and anticholinergic drugs
   c) Neuromuscular blockers
   d) Mydriactics and miotics
   e) Drugs used in myasthenia gravis
   f) Drugs used in Parkinsonism

3. **Pharmacology of drugs acting on cardiovascular system**
   a) Antihypertensives
   b) Anti-anginal drugs
   c) Anti-arrhythmic drugs
   d) Drugs used for therapy of Congestive Heart Failure
   e) Drugs used for hyperlipidaemias

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4. **Pharmacology of drugs acting on Central Nervous System**
   a) General anesthetics
   b) Sedatives and hypnotics
   c) Anticonvulsants
   d) Analgesic and anti-inflammatory agents
   e) *Psychotropic drugs*
   f) Alcohol and methyl alcohol
   g) CNS stimulants and cognition enhancers
   h) Pharmacology of local anaesthetics

5. **Pharmacology of Drugs acting on Respiratory tract**
   a) Bronchodilators
   b) Mucolytics
   c) Expectorants
   d) Antitussives
   e) NasalDecongestants

6. **Pharmacology of Hormones and Hormone antagonists**
   a) Thyroid and Antithyroid drugs
   b) Insulin, Insulin analogues and oral hypoglycemic agents
   c) Sex hormones and oral contraceptives
   d) Oxytocin and other stimulants and relaxants

7. **Pharmacology of autocoids and their antagonists**
   a) Histamines and Antihistaminics
   b) 5-Hydroxytryptamine and its antagonists
   c) Lipid derived autocoids and platelet activating factor

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2.5 COMMUNITY PHARMACY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope:** In the changing scenario of pharmacy practice in India, Community Pharmacists are expected to offer various pharmaceutical care services. In order to meet this demand, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling, health screening services for improved patient care in the community set up.

2. **Objectives:** Upon completion of the course, the student shall be able to –
   a. know pharmaceutical care services;
   b. know the business and professional practice management skills in community pharmacies;
   c. do patient counselling & provide health screening services to public in community pharmacy;
   d. respond to minor ailments and provide appropriate medication;
   e. show empathy and sympathy to patients; and
   f. appreciate the concept of Rational drug therapy.

   Text Books:
   a. Health Education and Community Pharmacy by N.S.Parmar.
   b. WHO consultative group report.
   c. Drug store & Business management by Mohammed Ali & Jyoti.

   Reference books:
   a. Handbook of pharmacy – health care.Edt. Robin J Harman. The Pharmaceutical press.
   b. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins.

   Special requirements:
   1. Either the college is having model community pharmacy (meeting the schedule N requirement) or sign MoU with at least 4-5 community pharmacies nearby to the college for training the students on dispensing and counselling activities.
   2. Special equipments like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.

3. **Scheme of evaluation (80 Marks)**

1.	Synopsis	10
2.	Major Experiment (Counselling of patients with specific diseases – emphasis should be given on Counselling introduction, content, process and conclusion)	30
3.	Minor Experiment(Ability to measure B.P/ CBG / Lung function)	15
4.	Prescription Analysis (Analyzing the prescriptions for probable drug interaction and ability to tell the management)	15
5.	Viva – Voce	10

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4. Lecture wise programme :

Topics

1 **Definition, scope, of community pharmacy**
Roles and responsibilities of Community pharmacist

2 **Community Pharmacy Management**
a) Selection of site, Space layout, and design
b) Staff, Materials- coding, stocking
c) Legal requirements
d) Maintenance of various registers
e) Use of Computers: Business and health care soft wares

3 **Prescriptions** – parts of prescription, legality & identification of medication related problems like drug interactions.

4 **Inventory control in community pharmacy**
Definition, various methods of Inventory Control
ABC, VED, EOQ, Lead time, safety stock

5 **Pharmaceutical care**
Definition and Principles of Pharmaceutical care.

6 **Patient counselling**
Definition, outcomes, various stages, barriers, Strategies to overcome barriers
Patient information leaflets- content, design, & layouts, advisory labels

7 **Patient medication adherence**
Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.

8 **Health screening services**
Definition, importance, methods for screening
Blood pressure/ blood sugar/ lung function and Cholesterol testing

9 **OTC Medication- Definition, OTC medication list & Counselling**

10 **Health Education**
WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients.
Commonly occurring Communicable Diseases, causative agents,
Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy,
Syphilis, Gonorrhea and AIDS
Balance diet, and treatment & prevention of deficiency disorders
Family planning – role of pharmacist

11 **Responding to symptoms of minor ailments**
Relevant pathophysiology, common drug therapy to,
Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Opthalmic symptoms, worms infestations.

12 **Essential Drugs concept and Rational Drug Therapy**
Role of community pharmacist

13 **Code of ethics for community pharmacists**

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2.6 PHARMACOTHERAPEUTICS - I (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
   a. the pathophysiology of selected disease states and the rationale for drug therapy;
   b. the therapeutic approach to management of these diseases;
   c. the controversies in drug therapy;
   d. the importance of preparation of individualised therapeutic plans based on diagnosis;
   e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
   f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
   g. summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
   h. discuss the controversies in drug therapy;
   i. discuss the preparation of individualised therapeutic plans based on diagnosis; and
   j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.

Reference Books

a. Pathologic basis of disease - Robins SL, W.B.Saunders publication.
b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
d. Applied Therapeutics:The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
f. Relevant review articles from recent medical and pharmaceutical literature.

3. **Detailed syllabus and lecture wise schedule :**

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Title of the topic

1 **Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, , Hyperlipidaemias , Electrophysiology of heart and Arrhythmias

2 **Respiratory system :** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases
Endocrine system : Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis

3 **General prescribing guidelines for**
a. Paediatric patients
b. Geriatric patients
c. Pregnancy and breast feeding

4 **Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial

5 **Introduction to rational drug use**
Definition, Role of pharmacist Essential drug concept Rational drug formulations

2.6 PHARMACOTHERAPEUTICS - I (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :
Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :
Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

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Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

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Third Year

3.1 PHARMACOLOGY – II (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, drugs acting on autacoids, respiratory system, GIT, immune system and hormones, and pharmacology of autocoids and hormones will be concentrated. In addition, pharmacology of chemotherapeutic agents, vitamines, essential minerals and principles of toxicology are also taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.

2. **Objectives of the Subject Upon completion of the subject student shall be able to:**
   a. understand the pharmacological aspects of drugs falling under the above mentioned chapters,
   b. carry out the animal experiments confidently,
   c. appreciate the importance of pharmacology subject as a basis of therapeutics, and
   d. correlate and apply the knowledge therapeutically.

Text books (Theory)

a. Tripathi, K. D. Essentials of medical pharmacology. 4th edition, 1999. Publisher: Jaypee, Delhi.
b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
c. Rang, H.P. and Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)

a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th edition, 1996. Publisher: Mc Graw Hill, Pergamon press.
b. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.
d. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.

Text books (Practical)

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

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Reference books (Practical) :

a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

3. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Pharmacology of Drugs acting on Blood and blood forming agents**
   a) Anticoagulants
   b) Thrombolytics and antiplatelet agents
   c) Haemopoietics and plasma expanders

2. **Pharmacology of drugs acting on Renal System**
   a) Diuretics
   b) Antidiuretics

3. **Chemotherapy**
   a) Introduction
   b) Sulfonamides and co-trimoxazole
   c) Penicillins and Cephalosporins
   d) Tetracyclins and Chloramphenicol
   e) Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics
   f) Quinolines and Fluroquinolines
   g) Antifungal antibiotics
   h) Antiviral agents
   i) Chemotherapy of tuberculosis and leprosy
   j) Chemotherapy of Malaria
   k) Chemotherapy of protozoal infections (amoebiasis, Giardiasis)
   l) Pharmacology of Anthelmintic drugs
   m) Chemotherapy of cancer (Neoplasms)

4 **Immunopharmacology**
Pharmacology of immunosuppressants and stimulants

5. **Principles of Animal toxicology**
Acute, sub acute and chronic toxicity

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6. **The dynamic cell: The structures and functions of the components of the cell**
   a) Cell and macromolecules: Cellular classification, subcellular organelles, macromolecules, large macromolecular assemblies
   b) Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information.
   c) DNA replication: General, bacterial and eukaryotic DNA replication.
   d) The cell cycle: Restriction point, cell cycle regulators and modifiers.
   e) Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors.

   The Gene: Genome structure and function:
   a) Gene structure: Organization and elucidation of genetic code.
   b) Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families.
   c) Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in pro and eukaryotes.

   RNA processing: rRNA, tRNA and mRNA processing.
   Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events
   Altered gene functions: Mutations, deletions, amplifications, LOH, traslocations, trinucleotide repeats and other genetic abnormalities. Oncogenes and tumor suppressor genes.
   The gene sequencing, mapping and cloning of human disease genes.
   Introduction to gene therapy and targeting.
   Recombinant DNA technology: principles. Processes (gene transfer technology) and applications

Books:

1 Molecular Biology of the Cell by Alberts B., Bray, D., Lewis, J., Raff M., Roberts, K and Watson, JD, 3rd edition.
2 Molecular Cell Biology By Lodish, H., Baltimore, D., Berk, A et al., 5th edition.
3 Molecular Biology by Turner, PC., McLennan, AG., Bates, AD and White MRH 2nd edition.
4 Genes VIII by Lewin, B., (2004)
5 Pharmaceutical Biotechnology, by Crommelin, DJA and Sindelar RD (1997)
6 Recombinant DNA by Watson, JD., Gilman, M., et al., (1996)
7 Biopharmaceutical: Biochemistry and Biotechnology by Walsh, G., (1998)

3.1 PHARMACOLOGY – II (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).
2. Study of physiological salt solutions used in experimental pharmacology.
3. Study of laboratory appliances used in experimental pharmacology.
4. Study of use of anesthetics in laboratory animals.
5. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
7. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
8. To record the dose response curve of Histamine using isolated guinea-pig ileum preparation.
9. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation.
10. To carry out bioassay of Histamine using isolated guinea-pig ileum preparation by interpolation method.
11. To carry out bioassay of Histamine using guinea-pig ileum preparation by three point method.
12. To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).
13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments:
    a) Analgesic property of drug using analgesiometer.
    b) Antiinflammatory effect of drugs using rat-paw edema method.
    c) Anticonvulsant activity of drugs using maximal electroshock and pentylene tetrazole methods.
    d) Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
    e) Locomotor activity evaluation of drugs using actophotometer and rotorod.
    f) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.

Scheme of Practical Examination:

	Sessionals	**Annual**
Identification	02	10
Synopsis	04	10
Major Experiment (Bioassay)	08	30
Minor Experiment (Interpretation of given Graph or simulated experiment)	04	10
Viva	02	10
Max Marks	**20**	**70**
Duration	**3hrs**	**4hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

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3.2 PHARMACEUTICAL ANALYSIS (THEORY)

Theory : 3 Hrs. /Week

1. **Quality Assurance:**
   a. Introduction, sources of quality variation, control of quality variation.
   b. Concept of statistical quality control.
   c. Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration.
   d. GLP, ISO 9000.
   e. Total quality management, quality review and documentation.
   f. ICH- international conference for harmonization-guidelines.
   g. Regulatory control.

2. **Chromatography:**
   Introduction, history, classification, separation techniques, choice of methods. The following techniques be discussed with relevant examples of pharmaceutical products involving principles and techniques of separation of drugs from excipients.
   a. **Column Chromatography**: Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography.
   b. **TLC**: Introduction, principle, techniques, R_f value and applications.
   c. **PC**: Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.
   d. **Ion-exchange chromatography**: Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.
   e. **HPLC**: Introduction, theory, instrumentation, and applications.
   f. **HPTLC**: Introduction, theory, instrumentation, and applications.
   g. **Gas Chromatography**: Introduction, theory, instrumentation-carrier gases, types of columns, stationary phases in GLC & GSC. Detectors- Flame ionization detectors, electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications.
   h. **Electrophoresis**: Principles of separation, equipment for paper and gel electrophoresis, and application.
   i. **Gel filtration** and **affinity chromatography**: Introduction, technique, applications.

3. **Electrometric Methods:**

Theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications be discussed on the following topics.

a. **Potentiometry**: Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischer titration.
b. **Conductometry**: Introduction, conductivity cell, conductometric titrations and applications.
c. **Polarography**: Instrumentation, DME, residual current, diffusion current and limiting current, polarographic wave, Ilkovic's equation, Effect of oxygen on polarographic wave, Polarographic maxima and suppressors and applications.
d. **Amperometric Titrations:** Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over potentiometry. Pharma applications.

4. **Spectroscopy:**

Theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of analytical techniques be discussed on:

a. **Absorption Spectroscopy:**

- Theory of electronic, atomic and molecular spectra. Fundamental laws of photometry, Beer-Lambert's Law, application and its deviation, limitation of Beer law, application of the law to single and multiple component analysis, measurement of equilibrium constant and rate constant by spectroscopy. Spectra of isolated chromophores, auxochromes, batho-chromic shift, hypsochromic shift, hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra.
  Instrumentation – Photometer, U.V.-Visible spectrophotometer – sources of U.V.-Visible radiations, collimating systems, monochromators, samples cells and following detectors-Photocell, Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations.

- **Infrared Spectroscopy**: Vibrational transitions, frequency – structure correlations, Infrared absorption bands, Instrumentation–IR spectrometer – sources of IR, Collimating systems, monochromators, sample cells, sample handling in IR spectroscopy and detectors– Thermocouple, Golay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy.

- **Fluorimetric Analysis:** Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry.

b. **Flame Photometry:** Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications.

c. **Atomic Absorption Spectrometry:** Introduction, Theory, types of electrodes, instrumentation and applications.

d. **Atomic Emission Spectroscopy**: Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection.

e. **NMR & ESR (introduction only):** Introduction, theoretical aspects and applications.

f. **Mass Spectroscopy: (Introduction only)** – Fragmentation, types of ions produced mass spectrum and applications.

g. **Polarimetry: (Introduction only)** – Introduction to optical rotatory dispersion, circular dichroism, polarimeter.

h. **X-RAY Diffraction: (Introduction only)** – Theory, reciprocal lattice concept, diffraction patterns and applications.

i. **Thermal Analysis**: Introduction, instrumentation, applications, and DSC and DTA.

3.2 PHARMACEUTICAL ANALYSIS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

1. Separation and identification of Amino Acids by Paper Chromatography.
2. Separation and identification of Sulpha drugs by TLC technique.
3. Effect of pH and solvent on the UV spectrum of given compound.
4. Comparison of the UV spectrum of a compound with that of its derivatives.
5. Determination of dissociation constant of indicators using UV-Visible spectroscopy.
6. Conductometric titration of mixture of acids with a strong base.
7. Potentiometric titration of a acid with a strong base.
8. Estimation of drugs by Fluorimetric technique.
9. Study of quenching effect in fluorimetry.
10. Colourimetric estimation of Supha drugs using BMR reagent.

11. Simultaneous estimation of two drugs present in given formulation.
12. Assay of Salicylic Acid by colourimetry.
13. Determination of Chlorides and Sulphates in Calcium gluconate by Nepheloturbidimetric Method.
14. Determination of Na/K by Flame Photometry.
15. Determination of pKa using pH meter.
16. Determination of specific rotation.
17. Comparison of the IR spectrum of a compound with that of its derivatives.
18. Demonstration of HPLC.
19. Demonstration of HPTLC.
20. Demonstration of GC-MS.
21. Demonstration of DSC.
22. Interpretation of NMR spectra of any one compound.

Reference Books:

1. Text Book of Pharm. Analysis by Higuchi. T and Hasen. E. B., New York Inter Science Publishers.
2. Quantitative Pharma. Analysis by Jenkins, The Blakiston division, New York.
3. Quantitative Drug Analysis, by Garrot. D, Chapman & Hall Ltd., London.
4. Undergraduate Instrumental Analysis by James. E., CBS Publishers.
5. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras.
6. Pharm Analysis by Skoog and West, Sounders Manipal College Publishing.
7. Text Book of Chemical Analysis, by A.I.Vogel, ELBS with Macmillan press, Hampshire.
8. Textbook of Pharm. Analysis by K.A.Connors, John Wiley & Sons, New York, Brisbane, Singapore.
9. Textbook of Pharm. Analysis (Practical) by Beckett & Stenlake, CBS Publishers, Delhi.
10. Textbook of Drug Analysis by P.D. Sethi., CBS Publishers, Delhi.
11. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore.
12. How to practise GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra.
13. The Science & Practice of Pharmacy by Remington Vol-I & II, Mack Publishing Co. Pennsylvania.
14. TLC by Stahl, Spring Verlay.
15. Text Book of Pharm. Chemistry by Chatten, CBS Publications.
16. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire.
17. I.P.-1996, The Controller of Publications, New Delhi.
18. BPC- Dept. of Health, U.K. for HMSO.
19. USP - Mack Publishing Co., Easton, PA.
20. The Extra Pharmacopoeia – The Pharm. Press, London.

Practicals

Title of the Experiment:

1 Study of agonistic and antagonistic effects of drugs using Guinea-pig ileum preparation.**
2 To study the effects of drugs on intestinal motility using frog's esophagus model*
3 To study the effects of drugs using rat uterus preparation.**
4 To study the anticonvulsant property of drugs (any one model).*
5 To study antihistaminic property of drug using histamine induced anaphylactic reaction in guinea pigs.
6 To study the apomorphine-induced compulsive behaviour (stereotypy) in mice.*
7 To study the muscle relaxant property of diazepam in mice using rotarod apparatus.*
8 To study the antiinflammatory property of indomethacin against carrageenan-induced paw oedema.**
9 To study the anxiolytic effect of diazepam in mice using mirrored-chamber apparatus.**
10 To demonstrate the effect of various drugs on the blood pressure and respiration of anaesthetized dog.
11 To study the effect of anthelmintics on earthworms.
12 To study the taming effect of chlorpromazine.*
13 To study the effects of drugs on vas deferense of the male rat.**
14 To study the effect of drugs on pesticide toxicity using rats as model.
15 To study the effect of drugs on heavy metal toxicity.

** indicate major experiment & * indicate minor experiment

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

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3.3 PHARMACOTHERAPEUTICS – II (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

2. **Objectives of the Subject Upon completion of the subject student shall be able to –**
   a. know the pathophysiology of selected disease states and the rationale for drug therapy
   b. know the therapeutic approach to management of these diseases;
   c. know the controversies in drug therapy;
   d. know the importance of preparation of individualised therapeutic plans based on diagnosis; and
   e. appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

   Text books (Theory)
   Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

   Reference books (Theory)
   a. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
   b. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
   c. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA]

3. **Detailed syllabus and lecture wise schedule :**
   Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases –

   Title of the topic

   1. **Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonarrhoea and Syphillis
   2 **Musculoskeletal disorders**
   Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
   3 **Renal system**
   Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders

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4 **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis

5 **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

3.3 PHARMACOTHERAPEUTICS – II (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment :

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

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3.4 PHARMACEUTICAL JURISPRUDENCE (THEORY)

Theory : 2 Hrs. /Week

1. **Scope of the Subject:** (4-6 lines): This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments are the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.

2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, and appreciate) –
   a. practice the Professional ethics;
   b. understand the various concepts of the pharmaceutical legislation in India;
   c. know the various parameters in the Drug and Cosmetic Act and rules;
   d. know the Drug policy, DPCO, Patent and design act;
   e. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
   f. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
   g. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

   Text books (Theory)

   Mithal , B M. Textbook of Forensic Pharmacy. Calcutta :National; 1988.

   Reference books (Theory)

   a. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
   b. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan ; 1995.
   c. Reports of the Pharmaceutical enquiry Committee
   d. I.D.M.A., Mumbai. DPCO 1995
   e. Various reports of Amendments.
   f. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
   g. Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

3. **Detailed syllabus and lecture wise schedule:**

   Title of the topic

   1. **Pharmaceutical Legislations** – A brief review.
   2. Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.
   3. **Drugs and Cosmetics Act, 1940,and its rules 1945.**
      Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y.
      Sales, Import, labeling and packaging of Drugs And Cosmetics Provisions Relating to Indigenous Systems.
      Constitution and Functions of DTAB,DCC,CDL.
      Qualification and duties –Govt. analyst and Drugs Inspector.

4. **Pharmacy Act –1948.**
   Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.
5. **Medicinal and Toilet Preparation Act –1955.**
   Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietory Preparations.
6. **Narcotic Drugs and Psychotropic substances Act-1985 and Rules**. Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.
7. **Study of Salient Features of Drugs and magic remedies Act and its rules.**
8. **Study of essential Commodities Act Relevant to drugs price control Order.**
9. **Drug Price control Order & National Drug Policy (Current).**
10. **Prevention Of Cruelty to animals Act-1960.**
11. **Patents & design Act-1970.**
12. **Brief study of prescription and Non-prescription Products.**

4. Assignments:

Format of the assignment

1. Minimum & Maximum number of pages
2. It shall be a computer draft copy
3. Reference(s) shall be included at the end.
4. Name and signature of the student
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min

Case studies relating to

1. Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
2. Various prescription and non-prescription products.
3. Medical and surgical accessories.
4. Diagnostic aids and appliances available in the market.

3.5 MEDICINAL CHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. Modern concept of rational drug design: A brief introduction to Quantitative Structure Activity Relationship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules.

   A study of the development of the following classes of drugs including SAR, mechanism of action, synthesis of important compounds, chemical nomenclature, brand names of important marketed products and their side effects.

2. Anti-infective agents
   a) Local anti-infective agents
   b) Preservatives
   c) Antifungal agents
   d) Urinary tract anti-infectives
   e) Antitubercular agents
   f) Antiviral agents and Anti AIDS agents
   g) Antiprotozoal agents
   h) Anthelmentics
   i) Antiscabies and Antipedicular agents
3. Sulphonamides and sulphones
4. Antimalarials
5. Antibiotics
6. Antineoplastic agents
7. Cardiovascular agents
   a) Antihypertensive agents
   b) Antianginal agents and vasodilators
   c) Antiarrhythmic agents
   d) Antihyperlipidemic agents
   e) Coagulants and Anticoagulants
   f) Endocrine
8. Hypoglycemic agents
9. Thyroid and Antithyroid agents
10. Diureties
11. Diagnostic agents
12. Steroidal Hormones and Adrenocorticoids

3.5 MEDICINAL CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

1. Assays of important drugs from the course content.
2. Preparation of medicinally important compounds or intermediates required for synthesis of drugs.
3. Monograph analysis of important drugs.
4. Determination of partition coefficients, dissociation constants and molar refractivity of compounds for QSAR analysis.

Reference Books:

a. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
b. William.O.Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.
c. Burgers, Medicinal Chemistry, M.E.,Welly Med.Chemistry M.E. Walffed Johnwilley and Sons, Wiley-interscience Publication, New York, Toranto.
d. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya, S.G. Publisher, 6, Dildayal Nagar, Varanasi -10.
e. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54.
f. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.
g. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.
h. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.
i. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.

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3.6 PHARMACEUTICAL FORMULATIONS (THEORY)

Theory : 2 Hrs. /Week

1. **Scope of the Subject:** Scope and objectives of the course: Subject deals with the formulation and evaluation of various pharmaceutical dosage forms.

2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, appreciate) –
   a. understand the principle involved in formulation of various pharmaceutical dosage forms;
   b. prepare various pharmaceutical formulation;
   c. perform evaluation of pharmaceutical dosage forms; and
   d. understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.

   Text books (Theory)
   a. Pharmaceutical dosage forms, Vol, I,II and III by lachman
   b. Rowlings Text book of Pharmaceutics
   c. Tutorial Pharmacy – Cooper &Gun

   Reference books (Theory)
   a. Remington's Pharmaceutical Sciences
   b. USP/BP/IP

3. **Detailed syllabus and lecture wise schedule:**

   Title of the topic

   1. Pharmaceutical dosage form- concept and classification
   2. **Tablets:** Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet.
   3. **Capsules;** Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatin capsules, quality control tests for soft gelatin capsules.
   4. **Liquid orals:** Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations
   5. **Parenterals** Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization
   6. **Ophthalmic preparations (Semi – Solids):** Introduction and classification Factors affecting absorption and anatomy of skin Packaging storage and labeling, Ointments Types of Ointment Base Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of preparation, Types Packaging
   7. Definition and concept of **Controlled and novel Drug delivery systems** with available examples, viz. parentral, trans dermal, buccal, rectal, nasal, implants, ocular

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3.6 PHARMACEUTICAL FORMULATIONS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments :

1. **Manufacture of Tablets**
   a. Ordinary compressed tablet-wet granulation
   b. Tablets prepared by direct compression.
   c. Soluble tablet.
   d. Chewable tablet.
2. **Formulation and filling of hard gelatin capsules**
3. **Manufacture of parenterals**
   a. Ascorbic acid injection
   b. Calcium gluconate injection
   c. Sodium chloride infusion.
   d. Dextrose and Sodium chloride injection/ infusion.
4. **Evaluation of Pharmaceutical formulations (QC tests)**
   a. Tablets
   b. Capsules
   c. Injections
5. **Formulation of two liquid oral preparations and evaluation by assay**
   a. Solution: Paracetamol Syrup
   b. Antacid suspensions- Aluminum hydroxide gel
6. **Formulation of semisolids and evaluation by assay**
   a. Salicyclic acid and benzoic acid ointment
   b. Gel formulation Diclofenac gel
7. **Cosmetic preparations**
   a. Lipsticks
   b. Cold cream and vanishing cream
   c. Clear liquid shampoo
   d. Tooth paste and tooth powders.
8. **Tablet coating (demonstration)**

Scheme of Practical Examination :

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

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Fourth Year

4.1 PHARMACOTHERAPEUTICS – III (THEORY)

Theory : 3 Hrs. /Week

1. **Scope :** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
   a. the pathophysiology of selected disease states and the rationale for drug therapy;
   b. the therapeutic approach to management of these diseases;
   c. the controversies in drug therapy;
   d. the importance of preparation of individualised therapeutic plans based on diagnosis;
   e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
   f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
   g. to summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
   h. to discuss the controversies in drug therapy;
   i. to discuss the preparation of individualised therapeutic plans based on diagnosis; and
   j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication
b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

Reference Books

a. Pathologic basis of disease - Robins SL, W.B.Saunders publication
b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication
c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
f. Relevant review articles from recent medical and pharmaceutical literature.

4.1 PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical : 3 Hrs./Week

Practicals:

Hospital postings for a period of at least 50 hours is required to understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy. Students are required to maintain a record of 15 cases observed in the ward and the same should be submitted at the end of the course for evaluation. Each student should present at least two medical cases they have observed and followed in the wards.

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

Title of the topic

1 **Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.
2 **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.
3 **Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
4 **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
5 Pain management including Pain pathways, neuralgias, headaches.
6 Evidence Based Medicine

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

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4.2 HOSPITAL PHARMACY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope**: In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug dispensing, manufacturing of parenteral preparations, drug information, patient counselling, and therapeutic drug monitoring for improved patient care.

2. **Objectives:** Upon completion of the course, the student shall be able to –
   a. know various drug distribution methods;
   b. know the professional practice management skills in hospital pharmacies;
   c. provide unbiased drug information to the doctors;
   d. know the manufacturing practices of various formulations in hospital set up;
   e. appreciate the practice based research methods; and
   f. appreciate the stores management and inventory control.

   Text books: (latest editions)
   a. Hospital pharmacy by William .E. Hassan
   b. A text book of Hospital Pharmacyby S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh

   References:
   a. WHO consultative group report.
   b. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
   c. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.

3. **Lecture wise programme :**

   Topics

   1 **Hospital - its Organisation and functions**
   2 **Hospital pharmacy-Organisation and management**
   a) Organizational structure-Staff, Infrastructure & work load statistics
   b) Management of materials and finance
   c) Roles & responsibilities of hospital pharmacist
   3 **The Budget – Preparation and implementation**
   4 **Hospital drug policy**
   a) Pharmacy and Therapeutic committee (PTC)
   b) Hospital formulary
   c) Hospital committees
   - Infection committee
   - Research and ethical committee

   d) developing therapeutic guidelines
   e) Hospital pharmacy communication - Newsletter

5 **Hospital pharmacy services**

a) Procurement & warehousing of drugs and Pharmaceuticals
b) Inventory control
Definition, various methods of Inventory Control
ABC, VED, EOQ, Lead time, safety stock
c) Drug distribution in the hospital
i) Individual prescription method
ii) Floor stock method
iii) Unit dose drug distribution method
d) Distribution of Narcotic and other controlled substances
e) Central sterile supply services – Role of pharmacist

6 **Manufacture of Pharmaceutical preparations**

a) Sterile formulations – large and small volume parenterals
b) Manufacture of Ointments, Liquids, and creams
c) Manufacturing of Tablets, granules, capsules, and powders
d) Total parenteral nutrition

7 **Continuing professional development programs**
Education and training

8 **Radio Pharmaceuticals – Handling and packaging**

9 **Professional Relations and practices of hospital pharmacist**

4.2 HOSPITAL PHARMACY (PRACTICAL)

Practical : 3 Hrs./Week

1. Assessment of drug interactions in the given prescriptions
2. Manufacture of parenteral formulations, powders.
3. Drug information queries.
4. Inventory control

List of Assignments:

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospital
4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
5. Different phases of clinical trials with elements to be evaluated.
6. Various sources of drug information and systematic approach to provide unbiased drug information.
7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

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Special requirements:

1. Each college should sign MoU with nearby local hospital having minimum 150 beds for providing necessary training to the students' on hospital pharmacy activities.
2. Well equipped with various resources of drug information.

Scheme of Practical Examination:

	Sessionals	**Annual**
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	**20**	**70**
Duration	**03hrs**	**04hrs**

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

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4.3 CLINICAL PHARMACY (THEORY)

Theory : 3 Hrs. /Week

1. **Objectives of the Subject :**

Upon completion of the subject student shall be able to (Know, do, appreciate) –

a. monitor drug therapy of patient through medication chart review and clinical review;
b. obtain medication history interview and counsel the patients;
c. identify and resolve drug related problems;
d. detect, assess and monitor adverse drug reaction;
e. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
f. retrieve, analyse, interpret and formulate drug or medicine information.

Text books (Theory)

a. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
b. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
c. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
d. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi etal, Orient Orient Langram Pvt.Ltd. ISSBN8125026

References

a. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
b. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
c. Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

2. **Detailed syllabus and lecture wise schedule:**

Title of the topic

1. **Definitions, development and scope of clinical pharmacy**
2. **Introduction to daily activities of a clinical pharmacist**
   a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
   b. Ward round participation
   c. Adverse drug reaction management
   d. Drug information and poisons information
   e. Medication history
   f. Patient counseling
   g. Drug utilisation evaluation (DUE) and review (DUR)
   h. Quality assurance of clinical pharmacy services

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3. **Patient data analysis**
   The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.
4. **Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results**
   a. Haematological, Liver function, Renal function, thyroid function tests
   b. Tests associated with cardiac disorders
   c. Fluid and electrolyte balance
   d. Microbiological culture sensitivity tests
   e. Pulmonary Function Tests
5. **Drug & Poison information**
   a. Introduction to drug information resources available
   b. Systematic approach in answering DI queries
   c. Critical evaluation of drug information and literature
   d. Preparation of written and verbal reports
   e. Establishing a Drug Information Centre
   f. Poisons information- organization & information resources
6. **Pharmacovigilance**
   a. Scope, definition and aims of pharmacovigilance
   b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
   c. Reporting, evaluation, monitoring, preventing & management of ADRs
   d. Role of pharmacist in management of ADR.
7. Communication skills, including patient counselling techniques, medication history interview, presentation of cases.
8. Pharmaceutical care concepts
9. Critical evaluation of biomedical literature
10. Medication errors

4.3 CLINICAL PHARMACY (PRACTICAL)

Practical : 3 Hrs./Week

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

a. Answering drug information questions (4 Nos)
b. Patient medication counselling (4 Nos)
c. Case studies related to laboratory investigations (4 Nos)
d. Patient medication history interview (3 Nos)

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Assignment:

Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

4.4 BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

Theory : 2 Hrs. /Week

1. Detailed syllabus and lecture wise schedule

1 **Research Methodology**

a) Types of clinical study designs:
Case studies, observational studies, interventional studies,

b) Designing the methodology

c) Sample size determination and Power of a study
Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study

d) Report writing and presentation of data

2 **Biostatistics**

2.1 a) Introduction

b) Types of data distribution

c) Measures describing the central tendency distributions- average, median, mode

d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

2.2 **Data graphics**

Construction and labeling of graphs, histogram, piecharts, scatter plots, semilogarthimic plots

2.3 **Basics of testing hypothesis**

a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.

b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)

c) Level of significance (Non-parametric data)- Sign test, Wilcoxan's signed rank test, Wilcoxan rank sum test, Mann Whitney U test, Kruskal-Wall is test (one way ANOVA)

d) Linear regression and correlation- Introduction, Pearsonn's and Spearmann's correlation and correlation co-efficient.

e) Introduction to statistical software: SPSS, Epi Info, SAS.

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2.4 **Statistical methods in epidemiology**

Incidence and prevalence, relative risk, attributable risk

3. Computer applications in pharmacy

Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics.

Computer In Community Pharmacy

Computerizing the Prescription Dispensing process

Use of Computers for Pharmaceutical Care in community pharmacy

Accounting and General ledger system

Drug Information Retrieval & Storage :

Introduction – Advantages of Computerized Literature Retrieval

Use of Computerized Retrieval

Reference books:

a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd edition, publisher Marcel Dekker Inc. NewYork.

b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3rd edition, McGraw Hill Publications 2006

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory : 3 Hrs. /Week

1. Biopharmaceutics

1. Introduction to Biopharmaceutics
   a. Absorption of drugs from gastrointestinal tract.
   b. Drug Distribution.
   c. Drug Elimination.

2. Pharmacokinetics

2. Introduction to Pharmacokinetics.
   a. Mathematical model
   b. Drug levels in blood.
   c. Pharmacokinetic model
   d. Compartment models
   e. Pharmacokinetic study.

3. One compartment open model.
   a. Intravenous Injection (Bolus)
   b. Intravenous infusion.

4. Multicompartment models.
   a. Two compartment open model.
   b. IV bolus, IV infusion and oral administration

5. Multiple – Dosage Regimens.
   a. Repititive Intravenous injections – One Compartment Open Model
   b. Repititive Extravascular dosing – One Compartment Open model
   c. Multiple Dose Regimen – Two Compartment Open Model

6. Nonlinear Pharmacokinetics.
   a. Introduction
   b. Factors causing Non-linearity.
   c. Michaelis-menton method of estimating parameters.

7. Noncompartmental Pharmacokinetics.
   a. Statistical Moment Theory.
   b. MRT for various compartment models.
   c. Physiological Pharmacokinetic model.

8. Bioavailability and Bioequivalence.
   a. Introduction.
   b. Bioavailability study protocol.
   c. Methods of Assessment of Bioavailability

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical : 3 Hrs./Week

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
2. Comparison of dissolution studies of two different marketed products of same drug.
3. Influence of polymorphism on solubility and dissolution.
4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
6. Bioavailability studies of some commonly used drugs on animal/human model.
7. Calculation of Ka, Ke, $t_1/2$, Cmax, AUC, AUMC, MRT etc. from blood profile data.
8. Calculation of bioavailability from urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. In vitro absorption studies.
11. Bioequivalency studies on the different drugs marketed.(eg) Tetracycline, Sulphamethoxzole, Trimethoprim, Aspirin etc., on animals and human volunteers.
12. Absorption studies in animal inverted intestine using various drugs.
13. Effect on contact time on the plasma protein binding of drugs.
14. Studying metabolic pathways for different drugs based on elimination kinetics data.
15. Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
16. Determination of renal clearance.

References:

a. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia.
c. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
d. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
e. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
f. Biopharmaceutics; By Swarbrick
g. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
h. Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

4.6 CLINICAL TOXICOLOGY (THEORY)

Theory : 2 Hrs. /Week

1. General principles involved in the management of poisoning
2. Antidotes and the clinical applications.
3. Supportive care in clinical Toxicology.
4. Gut Decontamination.
5. Elimination Enhancement.
6. Toxicokinetics.
7. Clinical symptoms and management of acute poisoning with the following agents –
   a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
   b) Opiates overdose.
   c) Antidepressants
   d) Barbiturates and benzodiazepines.
   e) Alcohol: ethanol, methanol.
   f) Paracetamol and salicylates.
   g) Non-steroidal anti-inflammatory drugs.
   h) Hydrocarbons: Petroleum products and PEG.
   i) Caustics: inorganic acids and alkali.
   j) Radiation poisoning
8. Clinical symptoms and management of chronic poisoning with the following agents – Heavy metals: Arsenic, lead, mercury, iron, copper
9. Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.
10. Plants poisoning. Mushrooms, Mycotoxins.
11. Food poisonings
12. Envenomations – Arthropod bites and stings.

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

a) CNS stimulants :amphetamine
b) Opioids
c) CNS depressants
d) Hallucinogens: LSD
e) Cannabis group
f) Tobacco

References:

a. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY – DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Willkins publication, London
b. V V Pillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad

Fifth year

5.1 CLINICAL RESEARCH (THEORY)

Theory : 3 Hrs. /Week

1. **Drug development process:**
   Introduction
   Various Approaches to drug discovery
   1. Pharmacological
   2. Toxicological
   3. IND Application
   4. Drug characterization
   5. Dosage form

2. **Clinical development of drug:**
   1. Introduction to Clinical trials
   2. Various phases of clinical trial.
   3. Methods of post marketing surveillance
   4. Abbreviated New Drug Application submission.
   5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
   6. Challenges in the implementation of guidelines
   7. Ethical guidelines in Clinical Research
   8. Composition, responsibilities, procedures of IRB / IEC
   9. Overview of regulatory environment in USA, Europe and India.
   10. Role and responsibilities of clinical trial personnel as per ICH GCP
       a. Sponsor
       b. Investigators
       c. Clinical research associate
       d. Auditors
       e. Contract research coordinators
       f. Regulatory authority
   11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
   12. Informed consent Process
   13. Data management and its components
   14. Safety monitoring in clinical trials.

References :

a. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.

b. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.

c. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.

d. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

e. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

f. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.

g. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

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5.2 PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

Theory : 3 Hrs. /Week

1. **Pharmacoepidemiology :**

Definition and scope:
Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

Measurement of outcomes in pharmacoepidemiology
Outcome measure and drug use measures
Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement

Concept of risk in pharmacoepidemiology
Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

Pharmacoepidemiological methods
Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods
Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

Sources of data for pharmacoepidemiological studies
Ad Hoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology
Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

2. **Phrmacoeconomics:**

Definition, history, needs of pharmacoeconomic evaluations

Role in formulary management decisions

Pharmacoeconomic evaluation
Outcome assessment and types of evaluation
Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods:
Cost – minimization, cost- benefit, cost – effectiveness, cost utility

3. **Applications of Pharmacoeconomics**

Software and case studies

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5.3 CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY)

Theory : 2 Hrs. /Week

1. **Introduction to Clinical pharmacokinetics.**

2. **Design of dosage regimens:**
   Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.

3. **Pharmacokinetics of Drug Interaction:**
   a. Pharmacokinetic drug interactions
   b. Inhibition and Induction of Drug metabolism
   c. Inhibition of Biliary Excretion.

4. **Therapeutic Drug monitoring:**
   a. Introduction
   b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight , disease, Interacting drugs).
   c. Indications for TDM. Protocol for TDM.
   d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
   e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.

5. **Dosage adjustment in Renal and hepatic Disease.**
   a. Renal impairment
   b. Pharmacokinetic considerations
   c. General approach for dosage adjustment in Renal disease.
   d. Measurement of Glomerular Filtration rate and creatinine clearance.
   e. Dosage adjustment for uremic patients.
   f. Extracorporeal removal of drugs.
   g. Effect of Hepatic disease on pharmacokinetics.

6. **Population Pharmacokinetics.**
   a. Introduction to Bayesian Theory.
   b. Adaptive method or Dosing with feed back.
   c. Analysis of Population pharmacokinetic Data.

7. **Pharmacogenetics**
   a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
   b. Genetic Polymorphism in Drug Transport and Drug Targets.
   c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations

APPENDIX-B

(See regulation 9)

CONDITIONS TO BE FULFILLED BY THE ACADEMIC TRAINING INSTITUTION

1) Any authority or institution in India applying to the Pharmacy Council of India for approval of courses of study for Pharm.D. and Pharm.D. (Post Baccalaureate) under sub-section (1) of section 12 of the Pharmacy Act, 1948 shall comply with the infrastructural facilities as prescribed by the Pharmacy Council of India from time to time.

2) Pharm.D. and Pharm.D. (Post Baccalaureate) programmes shall be conducted only in those institutions which -
   a) are approved by the Pharmacy Council of India for B.Pharm course as provided under section 12 of the Pharmacy Act, 1948;
   b) have 300 bedded hospital attached to it.

(i) Hospital Details

1. Institution with their own hospital of minimum 300 beds.
2. Teaching hospital recognised by the Medical Council of India or University, or a Government hospital not below the level of district headquarter hospital with 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
3. Corporate type hospital with minimum 300 beds with clearly defined Memorandum of Understanding including housing pharmacy practice department with minimum carpet area of 30 square feet per student along with consent to provide the professional manpower to support the programme.
4. Number of institutions which can be attached to one hospital shall be restricted by the student pharmacist to bed ratio of 1:10.

(ii) Speciality

a) Tertiary care hospitals are desirable
b) Medicine[compulsory], and any three specialization of the following
   1. Surgery
   2. Pediatrics
   3. Gynecology and obstetrics
   4. Psychiatry
   5. Skin and VD
   6. Orthopedics

(iii)Location of the Hospital

Within the same limits of Corporation or Municipality or Campus with Medical Faculty involvement as adjunct faculty.

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3) TEACHING STAFF REQUIREMENT

i) Staff Pattern : All faculty shall be full time. However part time perceptors in hospital shall be allowed.

ii) Subject wise specialisation of the Teaching Staff :

S.No.	Subject	Specialisation required
1.	Pharmacy Practice	M.Pharm in Pharmacy Practice or Pharmacology or Pharmaceutics.
2.	Human Anatomy & Physiology	M.Pharm in Pharmacology or Pharmacy practice
3.	Pharmaceutics (Dispensing & General Pharmacy)	M.Pharm in Pharmaceutics
4.	Pharmacognosy-I	M.Pharm in Pharmacognosy
5.	Pharmaceutical Organic Chemistry-I	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
6.	Pharmaceutical Inorganic Chemistry	M.Pharm in Pharmaceutical chemistry or Pharmaceutical Analysis or Quality assurance or Bulk Drug
7.	Pharmaceutical microbiology	M.Pharm in Pharmaceutics or Pharmaceutical Biotechnology
8.	Pathophysiology	M.Pharm Pharmacy practice or Pharmacology
9.	Applied Biochemistry & Clinical Chemistry	M.Pharm in Pharmacology or Pharmacy practice or Pharmaceutical chemistry
10.	Pharmacology-I	M.Pharm in Pharmacology or Pharmacy practice
11.	Pharmaceutical Jurisprudence	M.Pharm in Pharmaceutics
12.	Pharmacology-II	M.Pharm in Pharmacology or Pharmacy practice
13.	Pharmaceutical Dosage Forms	M.Pharm in Pharmaceutics or Industrial Pharmacy
14.	Pharmacotherapeutics –I, II and III	M.Pharm Pharmacy practice or Pharmacology
15.	Community Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics
16.	Hospital Pharmacy	M.Pharm in Pharmacy practice or Pharmacology or Pharmaceutics
17.	Clinical Pharmacy	M.Pharm in Pharmacy practice
18.	Computer Science or Computer Application in pharmacy	MCA
19.	Mathematics	M.Sc. (Maths)

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iii) Teaching Staff :

Department/Division	Name of the post	No.
Department of Pharmaceutics	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmaceutical Chemistry (Including Pharmaceutical Analysis)	Professor	1
	Asst. Professor	1
	Lecturer	3
Department of Pharmacology	Professor	1
	Asst. Professor	1
	Lecturer	2
Department of Pharmacognosy	Professor	1
	Asst. Professor	1
	Lecturer	1
Department of Pharmacy Practice	Professor	1
	Asst. Professor	2
	Lecturer	3

iv) Prescribed qualifications and experience for Professor, Assistant Professor, Lecturer and others :

Sl. No.	CADRE	QUALIFICATIONS	EXPERIENCE
1.	Lecturer	i) Basic degree in pharmacy (B.Pharm). ii) Registration as a pharmacist under the Pharmacy Act. iii) First Class Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm)	No minimum requirement.
2.	Assistant Professor	i) Basic degree in pharmacy (B.Pharm). ii) Registration as a pharmacist under the Pharmacy Act. iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm)	Three years experience in Teaching or Research at the level of Lecturer or equivalent.

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		iv) Ph.D. degree (with First Class degree either at Bachelor's or Master's level) in the appropriate branch of specialization in Pharmacy.	
3.	Professor	i) Basic degree in pharmacy (B.Pharm). ii) Registration as a pharmacist under the Pharmacy Act. iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm). iv) Ph.D. degree (with first Class either at Bachelor's or Master's level) in appropriate branch of specialization in Pharmacy.	i) Ten years experience in Teaching or Research. ii) Out of which five years must be as Assistant Professor.
4.	Director or Principal or Head of institute	i) Basic degree in pharmacy (B.Pharm). ii) Registration as a pharmacist under the Pharmacy Act. iii) Master's degree in appropriate branch of specialization in Pharmacy (M.Pharm) iv) Ph.D. degree (with first Class degree either at Bachelor's or Master's level in the appropriate branch of specialization in Pharmacy.	i) Fifteen years experience in Teaching or Research. ii) Out of which five years must be as Professor or above in Pharmacy. Desirable : Administrative experience in responsible position. The maximum age for holding the post shall be 65 years.

Note : If a class or division is not awarded at Master's level, a minimum of 60% marks in aggregate or equivalent cumulative grade point average shall be considered equivalent to first class or division, as the case may be.

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v) Workload of Faculty :

Professor – 8 hrs. per week

Assistant Professor – 12 hrs. per week

Lecturers – 16 hrs. per week

vi) Training of Pharmacy Practice Faculty :

a) Teaching staff will be trained as per the module prescribed by the Central Council.

b) Duration of training – Minimum 3 months.

c) Training sites – Institutions running pharmacy practice or Programmes for atleast five years.

d) Trainer – Professor or Assistant Professor with minimum of five years of clinical pharmacy teaching and practice experience.

4) NON-TEACHING STAFF :

Sl.No.	Designation	Required (Minimum)	Required Qualification
1	Laboratory Technician	1 for each Dept	D. Pharm
2	Laboratory Assistants or Laboratory Attenders	1 for each Lab (minimum)	SSLC
3	Office Superintendent	1	Degree
4	Accountant	1	Degree
5	Store keeper	1	D.Pharm or a Bachelor degree recognized by a University or institution.
6	Computer Data Operator	1	BCA or Graduate with Computer Course
7	Office Staff I	1	Degree
8	Office Staff II	2	Degree
9	Peon	2	SSLC
10	Cleaning personnel	Adequate	---
11	Gardener	Adequate	---

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5) ACCOMMODATION :

Suitable and sufficient accommodation with adequate ventilation, lighting and other hygienic conditions should be provided to the rooms for Principal or the Head of the department, office, class rooms, library, staff, staff common room, students common room, museum, laboratories, stores, etc.

At least two lecture halls alongwith eight laboratories as specified below should be provided for: —

1. Pharmaceutics and Pharmacokinetics Lab - 2
2. Life Science (Pharmacology, Physiology, Pathophysiology) - 2
3. Phytochemistry or Pharmaceutical Chemistry - 2
4. Pharmacy Practice - 2

Total = 8

In addition to the laboratories, balance room, aseptic room or cabinet, animal house and a machine room shall also be provided.

Floor area of the laboratory should not be less than 30 square feet per student required to work in the laboratory at any given time subject to a minimum of 750 square feet.

Laboratories should be fitted and constructed in a manner that these can be kept reasonably clean. Gas and water fittings, shelves, fuming cupboards be provided wherever necessary.

6. EQUIPMENT AND APPARATUS :

Department wise list of minimum equipments

A. DEPARTMENT OF PHARMACOLOGY :

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Microscopes	15
2	Haemocytometer with Micropipettes	20
3	Sahli's haemocytometer	20
4	Hutchinson's spirometer	01
5	Spygmomanometer	05
6	Stethoscope	05
7	Permanent Slides for various tissues	One pair of each tissue Organs and endocrine glands One slide of each organ system
8	Models for various organs	One model of each organ system
9	Specimen for various organs and systems	One model for each organ system
10	Skeleton and bones	One set of skeleton and one spare bone

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11	Different Contraceptive Devices and Models	One set of each device
12	Muscle electrodes	01
13	Lucas moist chamber	01
14	Myographic lever	01
15	Stimulator	01
16	Centrifuge	01
17	Digital Balance	01
18	Physical /Chemical Balance	01
19	Sherrington's Kymograph Machine or Polyrite	10
20	Sherrington Drum	10
21	Perspex bath assembly (single unit)	10
22	Aerators	10
23	Computer with LCD	01
24	Software packages for experiment	01
25	Standard graphs of various drugs	Adequate number
26	Actophotometer	01
27	Rotarod	01
28	Pole climbing apparatus	01
29	Analgesiometer (Eddy's hot plate and radiant heat methods)	01
30	Convulsiometer	01
31	Plethysmograph	01
32	Digital pH meter	01

II. Apparatus:

S.No	Name	Minimum required Nos.
1	Folin-Wu tubes	60
2	Dissection Tray and Boards	10
3	Haemostatic artery forceps	10
4	Hypodermic syringes and needles of size 15,24,26G	10
5	Levers, cannulae	20

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

B. DEPARTMENT OF PHARMACOGNOSY :

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Microscope with stage micrometer	15
2	Digital Balance	02
3	Autoclave	02

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4	Hot air oven	02
5	B.O.D.incubator	01
6	Refrigerator	01
7	Laminar air flow	01
8	Colony counter	02
9	Zone reader	01
10	Digital pH meter	01
11	Sterility testing unit	01
12	Camera Lucida	15
13	Eye piece micrometer	15
14	Incinerator	01
15	Moisture balance	01
16	Heating mantle	15
17	Flourimeter	01
18	Vacuum pump	02
19	Micropipettes (Single and multi channeled)	02
20	Micro Centrifuge	01
21	Projection Microscope	01

II. Apparatus:

S.No.	Name	Minimum required Nos.
1	Reflux flask with condenser	20
2	Water bath	20
3	Clavengers apparatus	10
4	Soxhlet apparatus	10
6	TLC chamber and sprayer	10
7	Distillation unit	01

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

C. DEPARTMENT OF PHARMACEUTICAL CHEMISTRY :

I. Equipment:

S.No.	Name	Minimum required Nos.
1	Hot plates	05
2	Oven	03
3	Refrigerator	01
4	Analytical Balances for demonstration	05
5	Digital balance 10mg sensitivity	10
6	Digital Balance (1mg sensitivity)	01
7	Suction pumps	06
8	Muffle Furnace	01

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9	Mechanical Stirrers	10
10	Magnetic Stirrers with Thermostat	10
11	Vacuum Pump	01
12	Digital pH meter	01
13	Microwave Oven	02

II. Apparatus:

S.No.	Name	Minimum required Nos.
1	Distillation Unit	02
2	Reflux flask and condenser single necked	20
3	Reflux flask and condenser double/ triple necked	20
4	Burettes	40
5	Arsenic Limit Test Apparatus	20
6	Nesslers Cylinders	40

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

D. DEPARTMENT OF PHARMACEUTICS :

I. Equipment:

S.No	Name	Minimum required Nos.
1	Mechanical stirrers	10
2	Homogenizer	05
3	Digital balance	05
4	Microscopes	05
5	Stage and eye piece micrometers	05
6	Brookfield's viscometer	01
7	Tray dryer	01
8	Ball mill	01
9	Sieve shaker with sieve set	01
10	Double cone blender	01
11	Propeller type mechanical agitator	05
12	Autoclave	01
13	Steam distillation still	01
14	Vacuum Pump	01
15	Standard sieves, sieve no. 8, 10, 12,22,24, 44, 66, 80	10 sets
16	Tablet punching machine	01
17	Capsule filling machine	01
18	Ampoule washing machine	01
19	Ampoule filling and sealing machine	01

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20	Tablet disintegration test apparatus IP	01
21	Tablet dissolution test apparatus IP	01
22	Monsanto's hardness tester	01
23	Pfizer type hardness tester	01
24	Friability test apparatus	01
25	Clarity test apparatus	01
26	Ointment filling machine	01
27	Collapsible tube crimping machine	01
28	Tablet coating pan	01
29	Magnetic stirrer, 500ml and 1 liter capacity with speed control	05 EACH 10
30	Digital pH meter	01
31	All purpose equipment with all accessories	01
32	Aseptic Cabinet	01
33	BOD Incubator	02
34	Bottle washing Machine	01
35	Bottle Sealing Machine	01
36	Bulk Density Apparatus	02
37	Conical Percolator (glass/copper/ stainless steel)	10
38	Capsule Counter	02
39	Energy meter	02
40	Hot Plate	02
41	Humidity Control Oven	01
42	Liquid Filling Machine	01
43	Mechanical stirrer with speed regulator	02
44	Precision Melting point Apparatus	01
45	Distillation Unit	01

II. Apparatus:

S.No	Name	Minimum required Nos.
1	Ostwald's viscometer	15
2	Stalagmometer	15
3	Desiccator*	05
4	Suppository moulds	20
5	Buchner Funnels (Small, medium, large)	05 each
6	Filtration assembly	01
7	Permeability Cups	05
8	Andreason's Pipette	03
9	Lipstick moulds	10

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

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E. DEPARTMENT OF PHARMACEUTICAL BIOTECHNOLOGY :

S.No.	Name	Minimum required Nos.
1	Orbital shaker incubator	01
2	Lyophilizer (Desirable)	01
3	Gel Electrophoresis (Vertical and Horizontal)	01
4	Phase contrast/Trinocular Microscope	01
5	Refrigerated Centrifuge	01
6	Fermenters of different capacity (Desirable)	01
7	Tissue culture station	01
8	Laminar airflow unit	01
9	Diagnostic kits to identify infectious agents	01
10	Rheometer	01
11	Viscometer	01
12	Micropipettes (single and multi channeled)	01 each
13	Sonicator	01
14	Respinometer	01
15	BOD Incubator	01
16	Paper Electrophoresis Unit	01
17	Micro Centrifuge	01
18	Incubator water bath	01
19	Autoclave	01
20	Refrigerator	01
21	Filtration Assembly	01
22	Digital pH meter	01

NOTE: Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and department.

F. DEPARTMENT OF PHARMACY PRACTICE :

Equipment:

S.No.	Name	Minimum required Nos.
1	Colorimeter	2
2	Microscope	Adequate
3	Permanent slides (skin, kidney, pancreas, smooth muscle, liver etc.,)	Adequate
4	Watch glass	Adequate
5	Centrifuge	1
6	Biochemical reagents for analysis of normal and pathological constituents in urine and blood facilities	Adequate
7	Filtration equipment	2
8	Filling Machine	1
9	Sealing Machine	1

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10	Autoclave sterilizer	1
11	Membrane filter	1 Unit
12	Sintered glass funnel with complete filtering assemble	Adequate
13	Small disposable membrane filter for IV admixture filtration	Adequate
14	Laminar air flow bench	1
15	Vacuum pump	1
16	Oven	1
17	Surgical dressing	Adequate
18	Incubator	1
19	PH meter	1
20	Disintegration test apparatus	1
21	Hardness tester	1
22	Centrifuge	1
23	Magnetic stirrer	1
24	Thermostatic bath	1

NOTE:

1. **Computers and Internet connection (Broadband), six computers for students with internet and staff computers as required.**
2. **Adequate number of glassware commonly used in the laboratory should be provided in each laboratory and the department.**

G. CENTRAL INSTRUMENTATION ROOM :

S.No.	Name	Minimum required Nos.
1	Colorimeter	01
2	Digital pH meter	01
3	UV- Visible Spectrophotometer	01
4	Flourimeter	01
5	Digital Balance (1mg sensitivity)	01
6	Nephelo Turbidity meter	01
7	Flame Photometer	01
8	Potentiometer	01
9	Conductivity meter	01
10	Fourier Transform Infra Red Spectrometer (Desirable)	01
11	HPLC	01
12	HPTLC (Desirable)	01
13	Atomic Absorption and Emission spectrophotometer (Desirable)	01
14	Biochemistry Analyzer (Desirable)	01
15	Carbon, Hydrogen, Nitrogen Analyzer (Desirable)	01
16	Deep Freezer (Desirable)	01
17	Ion- Exchanger	01
18	Lyophilizer (Desirable)	01

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APPENDIX-C

(See regulation 16)

INTERNSHIP

1) **SPECIFIC OBJECTIVES :**

i) to provide patient care in cooperation with patients, prescribers, and other members of an interprofessional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social cultural, economic, and professional issues, emerging technologies, and evolving biomedical, pharmaceutical, social or behavioral or administrative, and clinical sciences that may impact therapeutic outcomes.

ii) to manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health; to provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution; and to improve therapeutic outcomes of medication use.

iii) to promote health improvement, wellness, and disease prevention in co-operation with patients, communities, at-risk population, and other members of an interprofessional team of health care providers.

iv) to demonstrate skills in monitoring of the National Health Programmes and schemes, oriented to provide preventive and promotive health care services to the community.

v) to develop leadership qualities to function effectively as a member of the health care team organised to deliver the health and family welfare services in existing socio-economic, political and cultural environment.

vi) to communicate effectively with patients and the community.

2) **OTHER DETAILS :**

i) All parts of the internship shall be done, as far as possible, in institutions in India. In case of any difficulties, the matter may be referred to the Pharmacy Council of India to be considered on merits.

ii) Where an intern is posted to district hospital for training, there shall be a committee consisting of representatives of the college or university, and the district hospital administration, who shall regulate the training of such trainee. For such trainee a certificate of satisfactory completion of training shall be obtained from the relevant administrative authorities which shall be countersigned by the Principal or Dean of College.

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iii) Every candidate shall be required, after passing the final Pharm.D. or Pharm.D. (Post Baccalaureate) examination as the case may be to undergo compulsory rotational internship to the satisfaction of the College authorities and University concerned for a period of twelve months so as to be eligible for the award of the degree of Pharm.D. or Pharm.D. (Post Baccalaureate) as the case may be.

3. ASSESSMENT OF INTERNSHIP :

i) The intern shall maintain a record of work which is to be verified and certified by the preceptor (teacher practioner) under whom he works. Apart from scrutiny of the record of work, assessment and evaluation of training shall be undertaken by an objective approach using situation tests in knowledge, skills and attitude during and at the end of the training. Based on the record of work and date of evaluation, the Dean or Principal shall issue certificate of satisfactory completion of training, following which the university shall award the degree or declare him eligible for it.

ii) Satisfactory completion of internship shall be determined on the basis of the following:-

(1) Proficiency of knowledge required for each case management SCORE 0-5

(2) The competency in skills expected for providing Clinical Pharmacy Services SCORE 0-5

(3) Responsibility, punctuality, work up of case, involvement in patient care SCORE 0-5

(4) Ability to work in a team (Behavior with other healthcare professionals including medical doctors, nursing staff and colleagues). SCORE 0-5

(5) Initiative, participation in discussions, research aptitude. SCORE 0-5

Poor	Fair	Below Average	Average	Above Average	Excellent
0	1	2	3	4	5

A Score of less than 3 in any of above items will represent unsatisfactory completion of internship.

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APPENDIX-D

(See regulation 17)

CONDITIONS TO BE FULFILLED BY THE EXAMINING AUTHORITY

1. The Examining Authority shall be a statutory Indian University constituted by the Central Government/State Government/Union Territory Administration. It shall ensure that discipline and decorum of the examinations are strictly observed at the examination centers.

2. It shall permit the Inspector or Inspectors of the Pharmacy Council of India to visit and inspect the examinations.

3. It shall provide:-
   (a) adequate rooms with necessary furniture for holding written examinations;
   (b) well-equipped laboratories for holding practical examinations;
   (c) an adequate number of qualified and responsible examiners and staff to conduct and invigilate the examinations; and
   (d) such other facilities as may be necessary for efficient and proper conduct of examinations.

4. It shall, if so required by a candidate, furnish the statement of marks secured by a candidate in the examinations after payment of prescribed fee, if any, to the Examining Authority.

5. It shall appoint examiners whose qualifications should be similar to those of the teachers in the respective subjects as shown in Appendix–B.

6. In pursuance of sub–section (3) of section 12 of the Pharmacy Act, 1948, the Examining Authority shall communicate to the Secretary, Pharmacy Council of India, not less than six weeks in advance the dates fixed for examinations, the time-table for such examinations, so as to enable the Council to arrange for inspection of the examinations.

7. The Examining Authority shall ensure that examiners for conducting examination for Pharm.D. and Pharm.D. (Post Baccalaureate) programmes shall be persons possessing pharmacy qualification and are actually involved in the teaching of the Pharm.D. and Pharm.D. (Post Baccalaureate) programmes in an approved institution.

(ARCHNA MUDGAL)
Registrar-cum-Secretary
Pharmacy Council of India
New Delhi – 110002

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KAKATIYA UNIVERSITY, WARANGAL

SYLLUBUS FOR MASTER OF PHARMACY (M.PHARM)

TWO YEARS COURSE

From the academic year 2023-2024 onwards

FACULTY OF PHARMACEUTICAL SCIENCES,
KAKATIYA UNIVERSITY NAAC A+ Grade, WARANGAL

Dr.V.SwaroopaRani,

Vaagdevi College of Pharmacy, Ramnagar, Hanamkonda

Principal
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CHAPTER–I: REGULATIONS

1. ShortTitleandCommencement

These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M.Pharm.)Degree Program - Credit Based Semester System (CBSS) of the Pharmacy Council ofIndia,NewDelhi".TheyshallcomeintoeffectfromtheAcademicYear20203-24.Theregulations framed are subject tomodifications from time to time by the authorities of theKakatiya University.

2. Minimumqualificationforadmission

APassinthefollowingexaminations

a) B.PharmDegreeexaminationofanIndianuniversityestablishedbylawinIndiafroma

ninstitutionapprovedbyPharmacyCouncilofIndiaandhasscorednotlessthan55 %ofthemaximummarks(aggregate of 4years of B.Pharm.)

b) Every student, selected for admission to post graduate pharmacy program in any PCIapprovedinstitutionshould haveobtainedregistrationwiththeStatePharmacyCouncilorshould obtain the same within one month from the date of his/her admission, failing which theadmissionofthecandidateshallbecancelled.

Note: It is mandatory to submit a migration certificate obtained from the respective universitywhere the candidate hadpassedhis/herqualifyingdegree (B.Pharm.)

3. Durationoftheprogram

The program of study for M.Pharm. shall extend over a period of four semesters (two academicyears). The curricula and syllabi for the program shall be prescribed from time to time byPhamacyCouncilofIndia,NewDelhi.

4. Mediumofinstructionandexaminations

MediumofinstructionandexaminationshallbeinEnglish.

5. Workingdaysineachsemester

Eachsemestershallconsistofnotlessthan90workingdays.Theoddsemestersshallbeconductedfromth emonthofJune/JulytoNovember/Decemberandtheevensemestersshallbeconductedfromthemonthof December/JanuarytoMay/Juneineverycalendaryear.

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6. Attendance and progress

Acandidate isrequiredto put inat least 75%attendance in individualcoursesconsidering theory andpractical separately.The candidate shall complete the prescribedcourse satisfactorily tobeeligible toappearfortherespective examinations.

7. Program/Coursecreditstructure

As per the philosophyof Credit Based Semester System, certain quantumof academic work viz.theoryclasses, practicalclasses, seminars, assignments, etc. are measured interms ofcredits. Onsatisfactorycompletionofthe courses, a candidate earns credits. The amount ofcredit associatedwith a course is dependent upon the number of hours of instruction per week in that course.Similarly the credit associated with any of the other academic, co/extra- curricular activities isdependent upon the quantum of work expected to be put in for each of these activities perweek/peractivity.

CreditassignmentTheoryand

Laboratorycourses

Courses are broadly classified as Theoryand Practical. Theorycourses consist of lecture (L) andPractical(P)coursesconsistofhoursspentinthelaboratory.Credits(C)foracourseisdependent on the number of hours of instruction per week in that course, and is obtained byusingamultiplierof one(1)forlectureandamultiplierofhalf (1/2)forpractical (laboratory)hours.Thus, for example, a theorycourse having four lectures per week throughout the semestercarries a credit of 4. Similarly, a practical having four laboratory hours per week throughoutsemestercarries acreditof2.

Thecontacthoursofseminars,assignmentsandresearchworkshallbetreatedasthatofpracticalcoursesf or the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly,thecontacthoursofjournalclub,researchworkpresentationsanddiscussionswiththesupervi sorshallbeconsideredas theorycourseandmultipliedby1.

Minimumcreditrequirements

Theminimumcreditpoints requiredforthe awardofM. Pharm. degree is 95. However based onthe credit points earned by the students under the head of co-curricular activities, a student shallearn a maximum of 100 credit points. These credits are divided into Theory courses, Practical,Seminars,Assignments,Researchwork,Discussionswiththesupervisor,JournalclubandCo-Curricular activities over the durationoffour semesters. The credits are distributed semester-wiseasshown inTable 14.Coursesgenerallyprogressinsequence,buildingcompetenciesand

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their positioning indicates certain academic maturity on the part of the learners. Learners areexpectedtofollow the semester-wiseschedule ofcoursesgiveninthe syllabus.

8. Academicwork

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club,Discussion with thesupervisor,Researchwork presentation and Dissertation shall be maintainedbythedepartment/teachingstaffofrespectivecourses.

9. Courseofstudy

ThespecializationsinM.Pharmprogramisgiveninable1.

Table–1:ListofM.Pharm.SpecializationsandtheirCode

S.No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	IndustrialPharmacy	MIP
3.	PharmaceuticalChemistry	MPC
4.	PharmaceuticalAnalysis	MPA
5.	PharmaceuticalQualityAssurance	MQA
6.	PharmaceuticalRegulatoryAffairs	MRA
7.	PharmacyPractice	MPP
8.	Pharmacology	MPL
9.	Pharmacognosy	MPG

The courseofstudy for M.Pharmspecializations shall include Semester wise Theory& Practical asgiven in Table – 2 to 11. The number of hours to be devoted to each theory and practical courseinanysemestershallnotbelessthanthatshowninTable–2to11.

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Table–2:CourseofstudyforM.Pharm.(Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SemesterI					
MPH101T	ModernPharmaceutical AnalyticalTechniques	4	4	4	100
MPH102T	DrugDeliverySystems	4	4	4	100
MPH103T	ModernPharmaceutics	4	4	4	100
MPH104T	IPRandRegulatoryAffairs	4	4	4	100
MPH105P	Modern PharmaceuticalAnalyticalTechniquesPractical	6	3	6	100
MPH106P	Pharmaceutics-IPractical	6	3	6	100
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	700
SemesterII					
MPH201T	Advanced Biopharmaceutics& Pharmacokinetics	4	4	4	100
MPH202T	MolecularPharmaceutics (Nanotechnology&Targeted DrugDeliverySystems)	4	4	4	100
MPH203T	PharmaceuticalProduction Technology	4	4	4	100
MPH204T	Cosmetic andCosmeceuticals	4	4	4	100
MPH205P	AdvancedBioPharmaceuticsand PharmaocokineticsPractical	6	3	6	100
MPH206P	Pharmaceutics-IIPractical	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

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Table–3:CourseofstudyforM.Pharm.(IndustrialPharmacy)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SemesterI					
MIP101T	ModernPharmaceuticalAnalyticalTechniques	4	4	4	100
MIP102T	PharmaceuticalFormulationDevelopment	4	4	4	100
MIP103T	Noveldrugdeliverysystems	4	4	4	100
MIP104T	IPRandRegulatoryAffairs	4	4	4	100
MIP105P	PharmaceuticalAnalyticalTechniques PracticalI	6	3	6	100
MIP106P	IndustrialPharmacy-IPracticalII	6	3	6	100
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	700
SemesterII					
MIP201T	AdvancedBiopharmaceuticsandPharmacokinetics	4	4	4	100
MIP202T	ScaleupandTechnologyTransfer	4	4	4	100
MIP203T	PharmaceuticalProductionTechnology	4	4	4	100
MIP204T	EntrepreneurshipManagement	4	4	4	100
MIP205P	AdvancedBioPharmaceuticsandPharmaocokineticsPractical	6	3	6	100
MIP206P	IndustrialPharmacyPractical	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

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Table–4:CourseofstudyforM.Pharm.(PharmaceuticalChemistry)

CourseCode	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SemesterI					
MPC101T	ModernPharmaceutical AnalyticalTechniques	4	4	4	100
MPC1012T	Advanced Organic Chemistry-I	4	4	4	100
MPC103T	Advanced Medicinal Chemistry-I	4	4	4	100
MPC104T	ChemistryofNaturalProducts	4	4	4	100
MPC105P	ChemistryofNaturalProductsPractical	6	3	6	100
MPC106P	AdvancedMedicinal Chemistry–IPractical	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700
SemesterII					
MPC201T	SpectroscopicIdentificationofOrganic compounds	4	4	4	100
MPC202T	Advanced Organic Chemistry-II	4	4	4	100
MPC203T	AdvancedmedicinalChemistry-II	4	4	4	100
MPC204T	ComputerAidedDrugDesign	4	4	4	100
MPC205P	AdvancedOrganicChemistryPractical	6	3	6	100
MPC206P	AdvancedMedicinalChemistry-II Practical	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

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Table–5:CourseofstudyforM.Pharm.(PharmaceuticalAnalysis)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SemesterI					
MPA101T	ModernPharmaceutical AnalyticalTechniques	4	4	4	100
MPA102T	Advanced Pharmaceutical Analysis-I	4	4	4	100
MPA103T	PharmaceuticalValidation	4	4	4	100
MPA104T	FoodAnalysis	4	4	4	100
MPA105P	ModernPharmaceutical AnalyticalTechniques	6	3	6	100
MPA106P	AdvancedPharmaceuticalAnalysis-I	6	3	6	100
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	700
SemesterII					
MPA201T	AdvancedInstrumental Analysis	4	4	4	100
MPA202T	ModernBio-Analytical Techniques	4	4	4	100
MPA203T	QualityControland QualityAssurance	4	4	4	100
MPA204T	AdvancedPharmaceuticalAnalysis-II	4	4	4	100
MPA205P	AdvancedInstrumentalAnalysis	6	3	6	100
MPA206P	AdvancedPharmaceuticalAnalysis-II	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

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Table–6:CourseofstudyforM.Pharm.(PharmaceuticalQualityAssurance)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SemesterI					
MQA101T	Modern Pharmaceutical AnalyticalTechniques	4	4	4	100
MQA102T	QualityManagement System	4	4	4	100
MQA103T	QualityControlandQuality Assurance	4	4	4	100
MQA104T	ProductDevelopmentand TechnologyTransfer	4	4	4	100
MQA105P	ModernPharmaceuticalAnalytical techniques	6	3	6	100
MQA106P	QualityAsssuranceandQualityControl	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700
	SemesterII				
MQA201T	Hazards and Safety Management	4	4	4	100
MQA202T	PharmaceuticalValidation	4	4	4	100
MQA203T	Auditsand Regulatory Compliance	4	4	4	100
MQA204T	Pharmaceutical ManufacturingTechnology	4	4	4	100
MQA205P	PharmaceuticalValidation	6	3	6	100
MQA206P	PharmaceuticalManufacturingTechnology	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

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Table–7:CourseofstudyforM.Pharm.(RegulatoryAffairs)

Course Code	Course	Credit Hours	Credit Points	Hrs./ wk	Marks
	SemesterI				
MRA 101T	GoodRegulatoryPractices	4	4	4	100
MRA 102T	Documentationand RegulatoryWriting	4	4	4	100
MRA 103T	ClinicalResearch Regulations	4	4	4	100
MRA 104T	RegulationsandLegislationforDrugs& Cosmetics,MedicalDevices,Biological s & Herbals, and Food &NutraceuticalsInIndia andIntellectual PropertyRights	4	4	4	100
MRA 105P	RegulatoryAffairsPracticalI	6	3	6	100
MRA 106P	RegulatoryAffairsPracticalII	6	3	6	100
	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700
	SemesterII				
MRA 201T	RegulatoryAspectsofDrugs &Cosmetics	4	4	4	100
MRA 202T	RegulatoryAspectsofHerbal &Biologicals	4	4	4	100
MRA 203T	Regulatory Aspectsof MedicalDevices	4	4	4	100
MRA 204T	RegulatoryAspectsofFood &Nutraceuticals	4	4	4	100
MRA 205P	RegulatoryAffairsPracticalIII	6	3	6	100
MRA 206P	RegulatoryAffairsPracticalIV	6	3	6	100
	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

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Table–8:CourseofstudyforM.Pharm.(PharmacyPractice)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
	SemesterI				
MPP 101T	ClinicalPharmacyPractice	4	4	4	100
MPP 102T	Pharmacotherapeutics-I	4	4	4	100
MPP 103T	Hospital&Community Pharmacy	4	4	4	100
MPP 104T	ClinicalResearch	4	4	4	100
MPP 105P	PharmacyPracticePracticalI	6	3	6	100
MPP 106P	PharmacyPracticePracticalII	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700
	SemesterII				
MPP 201T	PrinciplesofQualityUseof Medicines	4	4	4	100
MPP 102T	PharmacotherapeuticsII	4	4	4	100
MPP 203T	ClinicalPharmacokineticsand TherapeuticDrugMonitoring	4	4	4	100
MPP 204T	Pharmacoepidemiology Pharmacoeconomics	4	4	4	100
MPP 205P	PharmacyPracticePracticalIII	6	3	6	100
MPP 206P	PharmacyPracticePracticalIV	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

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Table–9:Courseofstudyfor(Pharmacology)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SemesterI					
MPL 101T	ModernPharmaceutical AnalyticalTechniques	4	4	4	100
MPL 102T	AdvancedPharmacology-I	4	4	4	100
MPL103T	PharmacologicalandToxicologicalScreeningMethods-I	4	4	4	100
MPL 104T	CellularandMolecular Pharmacology	4	4	4	100
MPL 105P	PharmacologyPracticalI	6	3	6	100
MPL 106P	PharmacologyPracticalII	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700
SemesterII					
MPL 201T	AdvancedPharmacologyII	4	4	4	100
MPL202T	PharmacologicalandToxicologicalScreeningMethods-II	4	4	4	100
MPL 203T	PrinciplesofDrugDiscovery	4	4	4	100
MPL 204T	ClinicalResearchandPharmacovigilence	4	4	4	100
MPL 205P	PharmacologyPracticalIII	6	3	6	100
MPL 206P	PharmacologyPracticalIV	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

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Table–10:CourseofstudyforM.Pharm.(Pharmacognosy)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
	SemesterI				
MPG101T	ModernPharmaceutical AnalyticalTechniques	4	4	4	100
MPG102T	AdvancedPharmacognosy-1	4	4	4	100
MPG103T	Phytochemistry	4	4	4	100
MPG104T	IndustrialPharmacognostical Technology	4	4	4	100
MPG105P	AdvancedPharmacognosy-I	6	3	6	100
MPG106P	Phytochemistry	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700
	SemesterII				
MPG201T	AdvancedPharmacognosy-II	4	4	4	100
MPG202T	IndianSystemofMedicine	4	4	4	100
MPG203T	Herbalcosmetics	4	4	4	100
MPG204T	ClinicalResearchandPharmacovigilence	4	4	4	100
MPG205P	AdvancedPharmacognosy-II	6	3	6	100
MPG206P	HerbalCosmetics	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

Table–11:CourseofstudyforM.Pharm.IIISemester(CommonforAllSpecializations)

CourseCode	Course	CreditHours	CreditPoints
MRM301T	ResearchMethodologyand Biostatistics	4	4
-	Journalclub	1	1
-	Discussion/Presentation (ProposalPresentation)	2	2
-	ResearchWork	28	14
Total		35	21

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Table–12:CourseofstudyforM.Pharm.IVSemester(CommonforAllSpecializations)

Course Code	Course	CreditHours	CreditPoints
-	JournalClub	1	1
-	ResearchWork	31	16
-	Discussion/FinalPresentation	3	3
Total		35	20

Table–13:Semesterwisecreditsdistribution

Semester	CreditPoints
I	26
II	26
III	21
IV	20
Co-curricularActivities(AttendingConference,Scientific PresentationsandOtherScholarlyActivities)	Minimum=02Maximum=07*
TotalCreditPoints	Minimum=95 Maximum=100

*CreditPointsforCo-curricularActivities

TableNo-14GuidelinesforAwardingCreditPointsforCo-CurricularAwards

NameoftheActivity	MaximumCredit PointsEligible/ Activity
ParticipationinNationalLevel Seminar/Conference/Workshop/Symposium/TrainingPrograms (relatedtothespecializationofthestudent)	01
ParticipationininternationalLevelSeminar/Conference/Workshop/Symposium/TrainingPrograms(relatedtothespecializationofthe student)	02
AcademicAward/ResearchAwardfromState Level/NationalAgencies	01
AcademicAward/ResearchAwardfromInternational Agencies	02
Research/ReviewPublicationinNationalJournals (IndexedinScopus/WebofScience)	01
Research/ReviewPublicationinInternationalJournals (IndexedinScopus/WebofScience)	02

Journal: TheEditorialBoardOutsideIndia

*Thecreditpointsassignedforextracurricularandorco-curricularactivitiesshall begivenbythePrincipalsofthecollegesandthesameshallbesubmitted totheUniversity.Thecriteriato acquirethiscreditpointshallbedefined bytheUniversityfromtimetotime.

1. **ProgramCommittee**
   1. TheM. Pharm. programmeshallhaveaProgrammeCommitteeconstitutedbytheHeadoftheinstitutioninco nsultationwithalltheHeadsofthe departments.

   2. ThecompositionoftheProgrammeCommitteeshallbeasfollows:

A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M.Pharmspecialization and four student representatives (two fromeach academic year), nominated bytheHeadoftheinstitution.

3. DutiesoftheProgrammeCommittee:

i. Periodicallyreviewingtheprogressoftheclasses.
ii. Discussingtheproblemsconcerningcurriculum,syllabusandtheconductofclasses.
iii. Discussingwiththecourseteachersonthenatureandscopeofassessmentforthecourseandthesa meshallbeannouncedto thestudentsatthebeginningofrespectivesemesters.
iv. CommunicatingitsrecommendationtotheHeadoftheinstitutiononacademicmatters.
v. TheProgrammeCommitteeshallmeetatleasttwiceinasemesterpreferablyattheendofeachses sionalexamandbefore theendsemesterexam.

2. **Examinations/Assessments**

Theschemesforinternalassessment andendsemesterexaminationsaregiveninTable – 16.Endsemesterexaminations

The End Semester Examinations for each theory and practical course through semesters I to IVshall be conducted by the respective university and the marks/grades shall be submitted to theuniversity.

Note:IneachsemesterSeminar-50marksandAssignment-50marks(NonUniversityexam/Internalassessment)

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TableNo:16-SchemesforInternalAssessmentandEndSemester(Pharmaceutics-MPH)

CourseCode	Course	InternalAssessment			EndSemester Exams		TotalMarks
		Sessional Exams		Total	Marks	Duration	
		Marks	Duration				
SEMESTERI							
MPH101T	ModernPharmaceuticalAnalyticalTechniques	25	1.30Hr	25	75	3Hrs	100
MPH102T	DrugDelivery System	25	1.30Hr	25	75	3Hrs	100
MPH103T	ModernPharmaceutics	25	1.30Hr	25	75	3Hrs	100
MPH 104T	IPRandRegulatory Affair	25	1.30Hr	25	75	3Hrs	100
MPH 105P	ModernPharmaceutical Analyticaltechniques	25	3Hrs	25	75	4Hrs	100
MPH 106P	Pharmaceutics-I	25	3Hrs	25	75	4Hrs	100
-	Seminar /Assignment	100	-	-		3Hrs	100
Total							700
SEMESTERII							
MPH 201T	AdvancedBiopharmaceutics&Pharmacokinetics	25	1.30Hr	25	75	3Hrs	100
MPH 202T	MolecularPharmaceutics(NanoTechandTargetedDDS)	25	1.30Hr	25	75	3Hrs	100
MPH 203T	PharmaceuticalProductionTechnology	25	1.30Hr	25	75	3Hrs	100
MPH 204T	Cosmeticand Cosmeceutic Als	25	1.30Hr	25	75	3Hrs	100
MPH 205P	PharmaceuticsPracticalIII	25	3Hrs	25	75	4Hrs	100
MPH 206P	PharmaceuticsPracticalIV	25	3Hrs	25	75	4Hrs	100
	Seminar /Assignment	100				3Hrs	100
Total							700

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TableNo:17-SchemesforInternalAssessmentandEndSemester(IndustrialPharmacy-MIP)

Course Code	Course	InternalAssessment			EndSemesterExams		TotalMarks
		Sessional Exams		Total	Marks	Duration	
		Marks	Duration				
SEMESTERI							
MIP101T	ModernPharmaceutical AnalyticalTechniques	25	1.30Hr	25	75	3Hrs	100
MIP102T	PharmaceuticalFormulationDevelopment	25	1.30Hr	25	75	3 Hrs	100
MIP103T	NovelDrugDeliverySystems	25	1.30Hr	25	75	3 Hrs	100
MIP104T	IntellectualPropertyRightsand RegulatoryAffairs	25	1.30Hr	25	75	3 Hrs	100
MIP105P	PharmaceuticalAnalyticalTechniques	25	3Hrs	25	75	4Hr	100
MIP106P	Industrialpharmacy-I	25	3Hrs	25	75	4Hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700
Semester-II							
Total							700
MIP201T	AdvancedBiopharmaceutics Pharmacokinetics	25	1.30Hr	25	75	3 Hrs	100
MIP202T	ScaleupandTechnologyTransfer	25	1.30Hr	25	75	3 Hrs	100
MIP203T	PharmaceuticalProductionTechnology	25	1.30Hr	25	75	3 Hrs	100
MIP204T	EntrepreneurshipManagement	25	1.30Hr	25	75	3 Hrs	100
MIP205P	AdvancedBiopharmaceutics Pharmacokinetics	25	3hrs	25	75	4hrs	100
MIP206P	IndustrialPharmacy-II	25	3hrs	25	75	4hrs	100
-	Seminar /Assignment	100	-	-		3Hrs	100
Total							700

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TableNo:18-SchemesforInternalAssessmentandEndSemester(PharmaceuticalChemistry-MPC)

CourseCode	Course	InternalAssessment			EndSemester Exams		Total Marks
		SessionalExams		Total	Marks	Duration	
		Marks	Duration				
SEMESTERI							
MPC101T	ModernPharmaceuticalanalytical Techniques	25	1.30Hr	25	75	3Hrs	100
MPC102T	AdvancedOrganic Chemistry-I	25	1.30Hr	25	75	3Hrs	100
MPC103T	AdvancedMedicinal Chemistry-I	25	1.30Hr	25	75	3Hrs	100
MPC104T	ChemistryofNaturalProducts	25	1.30Hr	25	75	3Hrs	100
MPC105P	ChemistryOfNaturalProducts	25	3Hrs	25	75	4Hrs	100
MPC106P	AdvancedMedicinalChemistry-I	25	3hrs	25	75	4Hrs	100
-	Seminar /Assignment	100				3Hrs	100
Total							700
SEMESTERII							
MPC201T	SpectroscopicIdentificationofOrganiccompounds	25	1.30Hr	25	75	3 Hrs	100
MPC202T	AdvancedOrganic Chemistry-II	25	1.30Hr	25	75	3 Hrs	100
MPC203T	ComputerAidedDrugDeisgn	25	1.30Hr	25	75	3Hrs	100
MPC204T	AdvancedMedicinalChemistry&ScreeningMethods	25	1.30Hr	25	75	3Hrs	100
MPC205P	AdvancedOrganicChemistry	25	3hrs	25	75	4hrs	100
MPC206P	AdvancedMedicinalChemistry-II	25	3hrs	25	75	4hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700

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TableNo:19-SchemesforInternalAssessmentandEndSemester(Pharmaceutical Analysis-MPA)

CourseCode	Course	InternalAssessment			EndSemester Exams		Total Marks
		Continuous Mode	Sessional Exams	Total	Marks	Duration	
			Marks / Duration				
SEMESTERI							
MPA101T	ModernPharmaceuticalAnalyticalTechniques	25	1.30Hr	25	75	3Hrs	100
MPA102T	AdvancedPharmaceuticalAnalysis-I	25	1.30Hr	25	75	3Hrs	100
MPA103T	PharmaceutiCalValidation	25	1.30Hr	25	75	3Hrs	100
MPA104T	FoodAnalysis	25	1.30Hr	25	75	3Hrs	100
MPA105P	ModernPharmaceuticalAnalyticalTechniques	25	3Hrs	25	75	4Hrs	100
MPA106P	PharmaceutiCalAnalysis-I	25	3Hrs	25	75	4Hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700
SEMESTERII							
MPA201T	AdvancedInstrumentalAnalysis	25	1.30Hr	25	75	3Hrs	100
MPA202T	ModernBio-AnalyticalTechniques	25	1.30Hr	25	75	3Hrs	100
MPA203T	QualityControlandQualityAssurance	25	1.30Hr	25	75	3Hrs	100
MPA204T	AdvancedPharmaceutical Analysis-II	25	1.30Hr	25	75	3Hrs	100
MPA205P	AdvancedInstrumentalAnalysis-I	25	3Hrs	25	75	4Hrs	100
MPA206P	AdvancedPharmaceutical Analysis-II	25	3Hrs	25	75	4Hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700

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TableNo:20-SchemesforInternalAssessmentandEndSemester(PharmaceuticalQuality Assurance-MQA)

Course Code	Course	InternalAssessment			EndSemester Exams		Total Marks
		Sessional Exams		Total	Marks	Duration	
		Marks	Duration				
SEMESTERI							
MQA101T	ModernPharmaceuticalAnalyticalTechniques	25	1.30Hr	25	75	3Hrs	100
MQA102T	QualityManagementSystem	25	1.30Hr	25	75	3Hrs	100
MQA103T	QualityControland QualityAssurance	25	1.30Hr	25	75	3Hrs	100
MQA104T	ProductDevelopmentand TechnologyTransfer	25	1.30Hr	25	75	3Hrs	100
MQA105P	PharmaceuticalQualityAssurancePracticalI	25	3Hrs	25	75	4Hrs	100
MQA106P	PharmaceuticalQualityAssurancePractical -II	25	3Hrs	25	75	4Hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700
SEMESTERII							
MQA201T	HazardsandSafetyManagement	25	1.30Hr	25	75	3Hrs	100
MQA202T	PharmaceuticalValidation	25	1.30Hr	25	75	3Hrs	100
MQA203T	Audits RegulatoryCompliance	25	1.30Hr	25	75	3Hrs	100
MQA204T	PharmaceuticalManufacturingTechnology	25	1.30Hr	25	75	3Hrs	100
MQA205P	PharmaceuticalQuality AssurancePracticalIII	25	3Hrs	25	75	4Hrs	100
MQA206P	PharmaceuticalQualityAssurancePracticalIV	25	3Hrs	25	75	4Hrs	100
	Seminar/Assignment	100				3Hrs	100
Total							700

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TableNo:21-SchemesforInternalAssessmentandEndSemester(Pharmaceutical RegulatoryAffairs-MPA)

CourseCode	Course	InternalAssessment			EndSemester Exams		Total Marks
		Sessional Exams		Total	Marks	Duration	
		Marks	Duration				
SEMESTERI							
MRA101T	GoodPharmaceuticalPractices	25	1.30Hr	25	75	3Hrs	100
MRA102T	DocumentationandRegulatoryWriting	25	1.30Hr	25	75	3Hrs	100
MRA103T	ClinicalResearchRegulations	25	1.30Hr	25	75	3Hrs	100
MRA104T	RegulationsandLegislation Drugs&Cosmetics,MedicalDevices,Biologicals & Herbals, and Food&NutraceuticalsInIndiaandIntellectualPropertyRights	25	1.30Hr	25	75	3Hrs	100
MRA105T	PharmaceuticalRegulatory AffairsPracticalI	25	3Hrs	25	75	3Hrs	100
MRA106T	PharmaceuticalRegulatory AffairsPracticalII	25	3Hrs	25	75	3Hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700
Semester-II							
MRA201T	RegulatoryAspectsofDrugs & Cosmetics	25	1.30Hr	25	75	3Hrs	100
MRA202T	RegulatoryAspectsof Herbal&Biologicals	25	1.30Hr	25	75	3Hrs	100
MRA203T	RegulatoryAspectsofMedicalDevices	25	1.30Hr	25	75	3Hrs	100
MRA204T	RegulatoryAspectsofFood& Nutraceuticals	25	1.30Hr	25	75	3Hrs	100
MRA205P	PharmaceuticalRegulatoryAffairs PracticalIII	25	3Hrs	25	75	4Hrs	100
MRA206P	PharmaceuticalRegulatoryAffairs PracticalIV	25	3Hrs	25	75	4Hrs	100
	Seminar /Assignment	100				3Hrs	100
	Total						700

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TableNo:22-SchemesforInternalAssessmentandEndSemester(PharmacyPractice-MPP)

Course Code	Course	InternalAssessment			End Semester Exams		TotalMarks
		SessionalExams		Total	Marks	Duration	
		Marks	Duration				
SEMESTERI							
MPP101T	ClinicalPharmacyPractice	25	1.30Hr	25	75	3Hrs	100
MPP102T	Pharmacotherapeutics-I	25	1.30Hr	25	75	3Hrs	100
MPP103T	Hospital&CommunityPharmacy	25	1.30Hr	25	75	3Hrs	100
MPP104T	ClinicalResearch	25	1.30Hr	25	75	3Hrs	100
MPP105P	PharmacyPractice-IPractical-II	25	3 Hrs	25	75	4Hrs	100
MPP106P	PharmacyPractice-IIPractical-II	25	3Hrs	25	75	4Hrs	100
-	Seminar/Assignment	100	-	-	-	3Hrs	100
Total							700
SEMESTERII							
MPP201T	PrinciplesofQualityUseof Medicines	25	1.30Hr	25	75	3Hrs	100
MPP202T	PharmacotherapeuticsII	25	1.30Hr	25	75	3Hrs	100
MPP203T	ClinicalPharmacokineticsand Therapeutic DrugMonitoring	25	1.30Hr	25	75	3Hrs	100
MPP204T	Pharmacoepidemiology& Pharmacoeconomics	25	1.30Hr	25	75	3Hrs	100
MPP205P	PharmacyPractice-IPractical-III	25	3Hrs	25	75	4Hrs	100
MPP206P	PharmacyPractice-IIPractical-IV	25	3Hrs	25	75	4Hrs	100
-	Seminar/Assignment -	100	-	-	-	3Hrs	100
Total							700

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TableNo:23-SchemesforInternalAssessmentandEndSemester(Pharmacology-MPL)

Course Code	Course	InternalAssessment			EndSemester Exams		TotalMarks
		Sessional Exams		Total	Marks	Duration	
		Marks	Duration				
SEMESTERI							
MPL101T	ModernPharmaceuticalAnalyticalTechniques	25	1.30Hr	25	75	3Hrs	100
MPL102T	AdvancedPharmacology-I	25	1.30Hr	25	75	3Hrs	100
MPL103T	PharmacologicalandToxicologicalScreening Methods-I	25	1.30Hr	25	75	3Hrs	100
MPL104T	CellularandMolecular Pharmacology	25	1.30Hr	25	75	3Hrs	100
MPL105P	Pharmacology-I	25	3Hrs	25	75	4Hrs	100
MPL106P	Pharmacology-II	25	3Hrs	25	75	4Hrs	100
-	Seminar /Assignment -	100	-	-	-	3Hrs	100
Total							700
SEMESTERII							
MPL201T	AdvancedPharmacologyII	25	1.30Hr	25	75	3Hrs	100
MPL102T	Pharmacologicaland ToxicologicalScreening Methods-II	25	1.30Hr	25	75	3Hrs	100
MPL203T	PrinciplesofDrugDiscovery	25	1.30Hr	25	75	3Hrs	100
MPL204T	Clinicalresearchand pharmacovigilance	25	1.30Hr	25	75	3Hrs	100
MPL205P	Pharmacology-III	25	3Hrs	25	75	4Hrs	100
MPL206P	Pharmacology-IV	25	3Hrs	25	75	4Hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700

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TableNo:24-SchemesforInternalAssessmentandEndSemester(Pharmacognosy-MPG)

Course Code	Course	InternalAssessment			EndSemester Exams		TotalMarks
		Sessional Exams		Total	Marks	Duration	
		Marks	Duration				
SEMESTERI							
MPG101T	ModernPharmaceutical AnalyticalTechniques	25	1.30Hr	25	75	3Hrs	100
MPG102T	AdvancedPharmacognosy-1	25	1.30Hr	25	75	3Hrs	100
MPG103T	Phytochemistry	25	1.30Hr	25	75	3Hrs	100
MPG104T	IndustrialPharmacognostical Technology	25	1.30Hr	25	75	3Hrs	100
MPG105P	AdvancedPharmacognosy-I	25	3Hrs	25	75	4Hrs	100
MPG106P	Phytochemistry	25	3Hrs	25	75	4Hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700
SEMESTERII							
MPG201T	AdvancedPharmacognosy-II	25	1.30Hr	25	75	3Hrs	100
MPG102T	IndianSystemofMedicine	25	1.30Hr	25	75	3Hrs	100
MPG203T	Herbalcosmetics	25	1.30Hr	25	75	3Hrs	100
MPG204T	ClinicalResearchand Pharmacovigilence	25	1.30Hr	25	75	3Hrs	100
MPG205P	AdvancedPharmacognosy-II	25	3Hrs	25	75	4Hrs	100
MPG206P	HerbalCosmetics	25	3Hrs	25	75	4Hrs	100
-	Seminar/Assignment -	100	-	-	-	3Hrs	100
Total							700

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Tables–25:Schemesforinternalassessmentsandendsemesterexaminations(SemesterIII&IV)

Course Code	Course		InternalAssessment			EndSemester Exams		Total Marks
			SessionalExams		Total	Marks	Duration	
			Marks	Duration				
SEMESTERIII								
MRM301T	Research Methodologyand Biostatistics		25	1.30Hr	25	75	3Hrs	100
-	Journalclub		-	-	25	-	-	25
-	Discussion/ Presentation (Proposal Presentation)		-	-	50	-	-	50
-	Researchwork		-	-	-	250	4Hr	250
Total								425
SEMESTERIV								
-	Journalclub	-	-	-	25	-	-	25
-	Discussion/ Presentation (Proposal Presentation)	-	-	-	75	-	-	75
-	Researchworkand Colloquium	-	-	-	-	400	4Hr	400
Total								500

11.2.1.Sessional Exams

Two sessional exams shall be conducted for each theory / practical course as per the schedulefixedbythecollege(s).Theschemeofquestionpaperfortheoryandpracticalsessionalexaminations is given in the table. The average marks of two sessional exams shall be computedforinternalassessmentas pertherequirementsgivenintables.

12. PromotionandAwardofgrades

A studentshallbe declared PASSand eligibleforgetting gradein a course of M.Pharm.programme if he/she secures at least 50% marks in that particular course including internalassessment

13. CarryForwardofMarks

Incaseastudentfailstosecuretheminimum50%inanyTheoryorPracticalcourseasspecifiedin 12, then he/she shall reappearfor the end semester examination of that course. Howeverhis/her marks of the Internal Assessment shall be carried over and he/she shall be entitled forgrade obtainedbyhim/heronpassing.

14. ImprovementofInternalAssessment

A student shall have the opportunity to improve his/her performance only once in the sessionalexam component of theinternal assessment. The re-conduct of the sessional exam shall becompleted before the commencementofnextendsemestertheoryexaminations.

15. Re–ExaminationofEndSemesterExaminations

Reexaminationofendsemesterexaminationshallbeconductedaspertheschedulegivenintable 28.Theexactdatesofexaminationsshallbenotifiedfromtimetotime.

Table–26:Tentativescheduleofendsemesterexaminations

Semester	For RegularCandidates	ForFailedCandidates
IandIII	November/ December	May/June
IIandIV	May/June	November/December

16. AllowedtoKeepTerms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in 6.ATKTrules areapplicable asfollows:

A student shall be eligible to get his/her CGPA upon successful completion of the courses off toIV semesters.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Suchrulesarealsoapplicableforthosestudentswhofailtoregisterforexamination(s)of any course in any semester.

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17. GradingofPerformance

Lettergradesandgradepointsallocations:

Basedontheperformances,eachstudentshallbeawardedafinallettergradeattheendofthesemesterforeachcourse.Thelettergradesandtheir correspondinggradepointsaregiveninTable–28.

Table–27:LettergradesandgradepointsequivalenttoPercentageofmarksandperformances

Percentageof MarksObtained	LetterGrade	GradePoint	Performance
90.00–100	O	10	Outstanding
80.00–89.99	A	9	Excellent
70.00–79.99	B	8	Good
60.00–69.99	C	7	Fair
50.00–59.99	D	6	Average
Lessthan50	F	0	Fail
Absent	AB	0	Fail

Alearnerwhoremainsabsentforanyendsemesterexaminationshallbeassignedalettergradeof ABand a correspondinggrade pointofzero.He/she shouldreappearforthe saidevaluation/examinationinduecourse.

18. TheSemesterGradePointAverage(SGPA):

The performance of a student in a semester is indicated by a number called 'Semester GradePoint Average'(SGPA). TheSGPAistheweightedaverageofthegradepointsobtainedinallthe coursesby the student during the semester. Forexample, if a studenttakes five courses (Theory/Practical)ina semester withcreditsC1, C2, C3and C4 andthe student'sgrade points in these courses are G1,G2,G3andG4,respectively,andthenstudents'SGPAisequalto:

$$SGPA=\frac{C_1G_1+C_2G_2+C_3G_3+C_4G_4}{C_1+C_2+C_3+C_4}$$

The SGPA is calculated to two decimal points. It shouldbe noted that, the SGPA for anysemestershall takeintoconsideration the F and ABSgrade awarded in thatsemester. ForexampleifalearnerhasaForABS gradeincourse4,theSGPAshallthen becomputed as:

$$SGPA=\frac{C_1G_1+C_2G_2+C_3G_3+C_4*ZERO}{C_1+C_2+C_3+C_4}$$

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19. CumulativeGradePointAverage(CGPA):

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and isindicated in final grade report card/final transcript showing the grades of all IV semesters andtheir courses. The CGPA shall reflect the failed statusin case of F grade(s), till the course(s)is/arepassed. When the course(s) is/are passedby obtaining a pass grade on subsequent examination(s)the CGPA shall onlyreflect the new grade and not the fail grades earned earlier. The CGPA iscalculatedas:

$$CGPA=\frac{C_1S_1+C_2S_2+C_3S_3+C_4S_4}{C_1+C_2+C_3+C_4}$$

whereC1, C2, C3,….isthetotalnumberofcreditsforsemesterI,II,III,…. andS_1,S_2,S_3,....isthe SGPAofsemesterI,II,III,…..

20. DeclarationofClass

TheclassshallbeawardedonthebasisofCGPAasfollows:FirstClasswithDistinction=CGPAof. 7.5andabove

FirstClass =CGPAof6.00to 7.49

SecondClass=CGPA of 5.00to5.99

21. ProjectWork

Allthestudentsshallundertakeaproject under thesupervisionofateacher inSemester IIItoIV andsubmitareport.4copiesoftheprojectreportshallbesubmitted(typed&boundcopynotlessthan7 5pages).

The internal and external examiner appointed by the University shall evaluate the project at thetimeofthePracticalexaminationsofothersemester(s).Theprojectsshallbeevaluatedasperthe criteriagivenbelow.

EvaluationofDissertationBook:

Objective(s)oftheworkdone	50Marks
Methodologyadopted	150marks
ResultsandDiscussions	250Marks
ConclusionsandOutcomes	50Marks
Total	**500Marks**

EvaluationofPresentation:

Presentationofwork	100Marks
Communicationskills	50Marks
Questionandanswerskills	100Marks
Total	**250Marks**

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22. AwardofRanks:

RanksandMedalsshallbeawardedonthebasisof finalCGPA. However, candidateswho fail in one ormore courses during the M.Pharm program shall not be eligibleforaward of ranks.Moreover,the candidates should have completed the M. Pharmprogram in minimum prescribed number ofyears,(twoyears)fortheawardofRanks

23. DurationofthecompletionoftheProgramofthestudy

Theduration forthecompletionoftheprogramshallbe fixed asdoubletheactualdurationof theprogramandthestudentshavetopasswithinthesaidperiod,otherwisetheyhavetogetfreshRegistrati on.

24. RevaluationIRetotalingofanswerpapers

Thereisnoprovisionforrevaluationoftheanswerpapersinanyexamination.However,thecandidatesca napplyforretotalingbypayingprescribedfee.

25. Readmissionafterbreakofstudy

Candidatewho seeksre-admissiontotheprogramafterbreakofstudyhastogettheapproval from theuniversitybypayingacondonationfee.

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PHARMACEUTICS
(MPH)MODERNPHARMACEUTICALANALYTICALTECHNIQUES(MPH101T)I SEMESTER

THEORY **60HOURS**

Scope

This subject deals with various advanced analytical instrumental techniques for identification,characterizationandquantificationofdrugs.InstrumentsdealtareMassspectrometer,IR, HPLC,GC etc.

Objectives

Aftercompletionofcoursestudentisabletoknow,Chemical
- sandExcipients
- Theanalysisofvariousdrugsinsingleandcombinationdosageforms Theoreticalandpractical
- skills oftheinstruments

UNIT-I **10HRS**

a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated withUV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.

b. IRspectroscopy:Theory,ModesofMolecularvibrations,Samplehandling,Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affectingvibrationalfrequencies andApplicationsofIR spectroscopy

c. Spectroflourimetry:TheoryofFluorescence,Factorsaffectingfluorescence,Quenchers,Instrumentationand Applicationsoffluorescence spectrophotometer.

UNIT-II **8HRS**

MassSpectroscopy:Principle,Theory,InstrumentationofMassSpectroscopy,Differenttypesofionization likeelectronimpact,chemical,field,FABandMALDI,APCI,ESI,APPIAnalyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules,Metastableions,IsotopicpeaksandApplicationsofMassspectroscopy.

UNIT-III **12HRS**

Chromatography: Principle,apparatus,instrumentation,chromatographic parameters,factorsaffectingresolutionandapplications ofthefollowing:
a)Paperchromatographyb)ThinLayerchromatographyc)Ionexchangechromatographyd)Column chromatographye)Gaschromatography f)High PerformanceLiquidchromatography
g) Affinitychromatography

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UNIT-IV **10HRS**

Electrophoresis:Principle,Instrumentation,Workingconditions,factorsaffectingsepa rationandapplications ofthefollowing:
a)Paperelectrophoresisb)Gelelectrophoresisc)Capillaryelectrophoresisd)Zoneelectrophoresi se)Movingboundaryelectrophoresisf)Isoelectricfocusing

UNIT-V **10HRS**

a) Immunologicalassays:RIA(Radioimmunoassay),ELISA,Bioluminescenceassays.
b) Thermaltechniques:DSC,DTA,TGA,Principle,Instrumentation,factorsaffecting,advantages anddisadvantages andPharmaceuticalapplications.

UNIT-VI **8HRS**

NMR Spectroscopy: Quantum numbers and their role in NMR, Principle, instrumentation,solventrequirementsinNMR,Relaxationprocess,NMRsignalsinvariouscompou nds.Briefoutline ofFT-NMR andC^{13}NMR,applicationsofNMR Spectroscopy.

REFERENCEBOOKS:

1. SpectrometricIdentificationofOrganiccompounds-RobertMSilverstein,Sixthedition,JohnWiley&Sons,2004.
2. PrinciplesofInstrumentalAnalysis-Doglas ASkoog, F. JamesHoller,TimothyA. Nieman,5thedition,Easternpress,Bangalore,1998.
3. Instrumentalmethodsofanalysis–Willards,7thedition,CBSpublishers.
4. PracticalPharmaceuticalChemistry–BeckettandStenlake,VolII,4th edition,CBS Publishers,New Delhi,1997.
5. OrganicSpectroscopy-WilliamKemp,3rdedition,ELBS,1991.
6. QuantitativeAnalysisofDrugs inPharmaceuticalformulation- PDSethi, 3rdEdition,CBSPublishers,NewDelhi,1997.
7. PharmaceuticalAnalysis-Modernmethods–PartB-JWMunson,Volume11,MarcelDekkerSeries

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DRUGDELIVERYSYSTEMS
(MPH102T)

THEORY **60Hrs**

SCOPE

Thiscourseisdesignedtoimpartknowledgeontheareaofadvancesinnoveldrugdeliverysystems.

OBJECTIVES

Uponcompletionofthecourse,studentshallbeabletounderstandThevario

- usapproachesfordevelopmentofnoveldrugdeliverysystems.
- Thecriteria forselectionofdrugsandpolymers forthedevelopmentofdeliveringsystem
- TheformulationandevaluationofNoveldrugdeliverysystems..

UNIT-I **9Hrs**

Sustained Release (SR) and Controlled Release (CR) formulations: Introduction & basicconcepts,advantages/disadvantages,factorsinfluencing,Physicochemical&biologicalappr oaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulationcomputation of desired release rate and dose for controlled release DDS, pharmacokineticdesignforDDS–intermittent,zeroorder&firstorderrelease.

UNIT-II **9Hrs**

CarriersforDrugDelivery:Polymers/co-polymersintroduction,classification,characterization, polymerization techniques, application in CDDS / NDDS, biodegradable &naturalpolymers.

UNIT-III **9Hrs**

RateControlledDrugDeliverySystems:Types,Activation;ModulatedDrugDeliverySystems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activatedDrugDeliverySystemsFeedbackregulatedDrugDeliverySystems;Principles&Fundam entals.

UNIT-IV **9Hrs**

StudyofVariousDDS:Concepts,design,formulation&evaluationofcontrolledreleaseoralDDS,G RDDS,Mucoadhesiveandbuccal DDS,colon specific,liquidsustainedreleasesystems,Oculardeliverysystems.

UNIT-V **9Hrs**

Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers,TransdermalDrugDeliverySystems,Formulationandevaluation.

UNIT-VI **9Hrs**

Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation ofdelivery systems ofproteins andothermacromolecules.

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UNIT-VII **9Hrs**

Personalized Medicine: Introduction,Definition,Pharmacogenetics,Categories of Patientsfor Personalized Medicines, Customized drug deliverysystems, Bioelectronic Medicines, 3Dprintingofpharmaceuticals,Telepharmacy.6Hrs

REFERENCEBOOKS:

1. YW.Chien,NovelDrugDeliverySystems,2ndedition,revisedandexpanded,Marcel Dekker,Inc.,New York,1992.
2. Robinson, J. R.,LeeV.H. L,ControlledDrugDeliverySystems,MarcelDekker,Inc.,NewYork,1992.
3. Encyclopediaofcontrolleddelivery,Editor-EdithMathiowitz,PublishedbyWileyInterscience Publication,JohnWileyandSons,Inc,New York!Chichester/Weinheim
4. N.K.Jain,Controlled andNovelDrugDelivery,CBSPublishers&Distributors,NewDelhi,Firstedition1997(reprintin 2001).
5. S.P.VyasandR.K.Khar,ControlledDrugDelivery-conceptsandadvances,Vallabh Prakashan,New Delhi,Firstedition2002

JOURNALS

1. IndianJournalofPharmaceuticalSciences(IPA)
2. Indiandrugs(IDMA)
3. Journalofcontrolledrelease(ElsevierSciences)desirable
4. DrugDevelopmentandIndustrialPharmacy(Marcel&Decker)desirable

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MODERNPHARMACEUTICS
(MPH103T)

THEORY **60HRS**

Scope

Coursedesignedtoimpartadvancedknowledgeandskillsrequiredtolearnvariousaspectsandconceptsatpharmaceuticalindustries.

Objectives

Uponcompletionofthecourse,studentshallbeabletounderstandThee

- lementsofpreformulationstudies.
- TheActivePharmaceuticalIngredientsandGenericdrugProductdevelopment
- IndustrialManagementandGMPConsiderations.
- Optimization Techniques & Pilot Plant Scale Up
- TechniquesStabilityTesting,sterilizationprocess&packagingofdosageforms.

UNIT-I **14Hrs**

a. Preformulation Concepts – Drug Excipient interactions - different methods, kinetics ofstability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsionand Suspension, SMEDDS) preparation and stability. Large and small volume parental –physiologicalandformulationconsideration,Manufacturingand evaluation.

b. OptimizationtechniquesinPharmaceuticalFormulation:Conceptandparametersofoptimization,Optimizationtechniquesinpharmaceuticalformulationandprocessing.Statisticaldesign,Responsesurfacemethod,Contourdesigns,Factorialdesignsandapplicationinformulation

UNIT-II **10Hrs**

Validation:IntroductiontoPharmaceuticalValidation,Scope&meritsandtypesofValidation, Validation and calibration ofMaster plan, ICH & WHO guidelines for calibrationand validation of equipments(Tablet machine, Coating pan, auto clave, FBD, aseptic room),Validationofspecificdosageform(solidsandliquid).Governmentregulation,ManufacturingProcessModel,DQ,IQ,OQ &PQoffacilities.

UNIT-III **10Hrs**

cGMP & Industrial Management: Objectives and policies of currentgood manufacturingpractices,layoutofbuildings,services,equipmentsandtheirmaintenance.Productionmanagement: Production organization, materials management, handling and transportation,inventory management and control, production planning and control, Sales forecasting,budgetandcostcontrol,industrialandpersonalrelationship.ConceptofTotalQualityManagement.

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UNIT-IV **10Hrs**

Compression, compaction and consolidation: Physics of tablet compression, Basic principlesof interaction, compression and consolidation, effect ofload, friction, distribution of forces incompaction, force volume relationship, Heckel plots, compaction profile, measurement ofcompressionwithstraingauge.

UNIT-V **10Hrs**

Dissolutiontesting:studyoffactorsinfluencingdissolution,Dissolutiondataanalysismathematical models ofdrugrelease (HiguchiandPeppas)

UNIT-VI **6Hrs**

Linearity(Regression) Concept ofsignificance, Standard deviation, standard error Chisquaretest,studentsT-test,ANOVA(onewayandtwo way)testandPvalue.

REFERENCEBOOKS:

1. TheoryandPracticeofIndustrialPharmacyByLachmannandLibermann
2. Pharmaceuticaldosageforms:TabletsVol.1-3byLeonLachmann.
3. PharmaceuticalDosageforms:Dispersesystems,Vol,1-2;ByLeonLachmann.
4. PharmaceuticalDosageforms:ParenteralmedicationsVol.1-2;ByLeonLachmann.
5. ModernPharmaceutics;ByGillbertandS.Banker.
6. Remington'sPharmaceuticalSciences.
7. AdvancesinPharmaceuticalSciencesVol.1-5;ByH.S.Bean&A.H.Beckett.
8. PhysicalPharmacy;ByAlfredmartin
9. Bentley'sTextbookofPharmaceutics–byRawlins.
10. GoodmanufacturingpracticesforPharmaceuticals:Aplanfortotalqualitycontrol,Secondeditio n;BySidneyH.Willig.
11. QualityAssuranceGuide;ByOrganizationofPharmaceuticalproducersofIndia.
12. Drugformulationmanual;ByD.P.S.KohliandD.H.Shah.Easternpublishers,NewDelhi.
13. HowtopracticeGMPs;ByP.P.Sharma.VandhanaPublications,Agra.
14. PharmaceuticalProcessValidation;ByFra.R.BerryandRobertA.Nash.
15. PharmaceuticalPreformulations;ByJ.J.Wells.
16. Appliedproductionandoperationsmanagement;ByEvans,Anderson,SweeneyandWilliams.
17. EncyclopaediaofPharmaceuticaltechnology,VolI–III.

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IPR AND REGULATORYAFFAIRS
(MPH104T)

THEORY **60Hrs**

Scope

Course designed to impartadvanced knowledge and skills required to learn the conceptofgeneric drug and their development, various regulatory filings in different countries, differentphases of clinical trials and submitting regulatory documents: filing process of IND, NDA andANDA

- Toknowtheapprovalprocess
- Toknowthechemistry,manufacturingcontrolsandtheirregulatoryimportanceTole
- arnthedocumentationrequirements
- Tolearntheimportance

Objectives:

Uponcompletionofthecourse,itisexpectedthatthestudentswillbeabletounderstandTheConcep

- tsofinnovatorandgeneric
- drugs,drugdevelopmentProcessTheRegulatoryguidance'sandguidelinesforfilingandappr
- ovalprocessPreparationofDossiersandtheirsubmissiontoregulatoryagenciesindifferentcou
- ntriesPostapproval regulatory requirements for actives and drug
- productsSubmissionofglobaldocumentsinCTD/eCTDformatsClinicaltrialsrequirementsf
- orapprovalsforconductingclinicaltrials
- Pharmacovigilenceandprocessofmonitoring inclinicaltrials.

UNIT-I **10Hrs**

Drugproductdevelopment:Activepharmaceuticalingredients,drugmasterfile(DMF)andimpurities. Generic product development: Introduction, Hatch-Waxman act and amendments,GUDUFA, ANDA (505j), ANDA approval process. New drug application (505B1 and 505B2).NDAapprovalprocessincludingIND.Scaleupandpostapprovalchanges(SUPAC).Bioequiva lenceandBioavailability,differenttypesofstudiesfordrugproductapproval.

UNIT-II **10Hrs**

ICH- Guidelines of ICH – Q7 to Q11, M9. Clinical Trials. HIPPA – new, requirements toclinicalstudyprocess,Parmacovigilance safetymonitoringinclinicaltrials.

UNIT-III **10Hrs**

ANDA for generic drugs ways and means of US registration for foreign drugs. CMC, Postapprovalregulatoryaffairs.Regulationforcombinationproducts,medicaldevices&Biosimilars.

UNIT-IV **10Hrs**

BriefintroductiontoCDSCO,WHO,USFDA,EMEA,TGA,MHRA,MCC,ANVISA.

UNIT-V **10Hrs**

Definitions, Need for Patenting, Types of Patents, Conditions to be satisfied by an inventionto be Patentable, introduction to patent and patent search. Parts of Patent. Filing of patents.The essential elements of patent. Guidelines for preparation of laboratory notebook, Non-obviousnessinpatent.

UNIT-VI **10Hrs**

Copy right, Trademark, Geographical indication acts, Patentlitigation, 180 days marketexclusivityandDoctrineofequivalents.

REFERENCEBOOKS

1. GenericDrugProductDevelopment,SolidOralDosageforms,LeonShargeland IsaderKaufer,MarcelDekkerseries,Vol.143
2. ThePharmaceuticalRegulatoryProcess,Second EditionEditedbyIraR.BerryandRobertP.Martin, Drugs and the Pharmaceutical Sciences,Vol.185,InformaHealthcarePublishers.
3. NewDrugApprovalProcess:AcceleratingGlobalRegistrationsByRichardAGuarino, MD,5thedition,Drugs andthePharmaceuticalSciences,Vol.190.
4. Guidebookfordrugregulatorysubmissions/SandyWeinberg.ByJohnWiley&Sons.Inc.
5. FDAregulatoryaffairs:aguideforprescriptiondrugs,medicaldevices,andbiologics/editedByDouglas J.Pisano,DavidMantus.
6. ClinicalTrialsandHumanResearch:APracticalGuidetoRegulatoryComplianceByFayA. RozovskyandRodneyK.Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

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MODERNPHARMACEUTICALANALYTICALTECHNIQUESPRACTICALS (MPH105P)

1. Analysisofpharmacopoeialcompoundsandtheirformulationsby UV Visspectrophotometer(Minimum4Experiments)
2. Simultaneousestimationofmulticomponentcontainingformulationsby UV/HPLCspectrophotometry(Minimum4Experiments)
3. ExperimentsbasedonHPLC
4. ExperimentsbasedonGasChromatography
5. Estimationofriboflavin/quininesulphatebyfluorimetry
6. Estimationofsodium/potassiumbyflamephotometry

PHARMACEUTICS-I PRACTICALS(MPH106P)

1. Tocarryoutpreformulationstudiesofdrugs,effectofsurfactantsandpHonthesolubilityofdrugs, compatibilityevaluationofdrugs andexcipients byDSC andFTIR.
2. Formulation andevaluation of SR/CRTabletsandcompareIn-Vitrodissolution profileofSR/CRMarketedformulation.
3. Formulationandevaluationosmoticallycontrolled DDS
4. PreparationandevaluationofFloatingDDS-hydrodynamicallybalancedDDS
5. FormulationandevaluationofMucoadhesivetablets.
6. Formulationandevaluationoftransdermalpatches.
7. Stabilitystudiesofdrugsinsolutionsandsoliddosageformsaccordingto ICH guidelines.
8. Tostudytheeffectofcompressionalforce,particlesizeand bindersontabletsdisintegrationtime anddissolutionofatablet.
9. TostudyMicromeriticpropertiesofpowdersandgranulation.
10. AnalysisofdrugreleasefromCRtablets,Higuchi,Peppasplot,zeroorder.Similarityfactordetermination
11. Preparationandevaluationofdifferentpolymericmembranes.
12. ValidationofTabletmachine,coatingpan,dryers,autoclave

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SEMESTER-II
ADVANCEDBIOPHARMACEUTICS&PHARMACOKINETICS(MPH201T)

THEORY **60Hrs**

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, doseadjustmentsandtoapplybiopharmaceuticstheoriesinpracticalproblemsolving.Basictheoretical discussions of the principles of biopharmaceutics and pharmacokinetics are providedtohelpthestudents'toclarifytheconcepts.

Objectives

Uponcompletionofthiscourseitisexpectedthatstudentswillbeableunderstand,Theb

- asicconceptsinbiopharmaceuticsandpharmacokinetics.
- Theuserawdataandderivethepharmacokineticmodelsandparametersthebestdescribetheprocesso fdrugabsorption,distribution,metabolismandelimination.
- Thecriticalevaluationofbiopharmaceuticstudiesinvolvingdrugproductequivalency.Thedesignandevaluati
- onofdosageregimensofthedrugsusingpharmacokineticand biopharmaceuticparameters.
- Thepotentialclinicalpharmacokineticproblemsandapplicationofbasicsofpharmacokinetic

UNIT-I **10Hrs**

DrugAbsorptionfrom theGastrointestinal Tract: Gastrointestinal tract, Mechanism of drugabsorption,Factorsaffectingdrugabsorption,pH–partitiontheoryofdrugabsorption.Formulationandphysicochemicalfactors:Dissolutionrate,Dissolution process,Noyes–Whitneyequation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption:role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as adosageform,Capsuleasadosageform,Tabletasadosageform,Dissolutionmethods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data.Transportmodel:Permeability-Solubility-ChargeStateandthepHPartitionHypothesis,Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment,Tight-JunctionComplex.

UNIT-II **10Hrs**

Biopharmaceutic considerations in drug product design and In Vitro Performance: Introduction,biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption,physicochemical nature of the drug, formulation factors affecting drug product performance,

invitro:dissolutionanddrugreleasetesting,compendialmethodsofdissolution,alternativemethods ofdissolutiontesting,meeting dissolutionrequirements, problems ofvariable controlindissolution testing performance ofdrug products. In vitro–in vivo correlation, dissolution profilecomparisons.

UNIT-III **10Hrs**

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling:one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model:twocompartment-modelinbrief.

UNIT-IV **10Hrs**

Non-linearpharmacokinetics:causeofnon-linearity,Michaelis–Mentenequation,estimation of Kmax and Vmax. Noncompartmental Pharmacokinetics- statistical momenttheoryandphysiologicalpharmacokineticmodel.Alteredpharmacokineticsinrenalandhepaticdiseases.Drug interactions: introduction,theeffect ofproteinbindingoninteractions, theeffect of tissue-binding on interactions, cytochrome p450-based drug interactions, and druginteractionslinkedtotransporters.

UNIT-V **10Hrs**

DrugProductPerformance,InVivo:BioavailabilityandBioequivalence:drugproductperformance, purpose of bioavailability studies, relative and absolute availability. Methodsforassessingbioavailability,bioequivalencestudies,designandevaluationofbioequivalencestudies,studydesigns,crossoverstudydesigns,evaluationofthedata,bioequivalenceexample, studysubmissionand drug review process. Biopharmaceuticsclassificationsystem,methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilardrugproducts),clinicalsignificanceofbioequivalencestudies,specialconcernsinbioavailabilityandbioequivalence studies,genericsubstitution.

UNIT-VI **10Hrs**

ApplicationofPharmacokinetics:ChronoPharmacokinetics,Modified-ReleaseDrugProducts, Targeted Drug Delivery Systems and Biotechnological Products. Introduction toPharmacokineticsandpharmacodynamicsofbiotechnology drugsProteinsandpeptides,Monoclonalantibodies,Oligonucleotides,Vaccines(immunotherapy),Genetherapies.**10Hrs**

REFERENCEBOOKS:

1. BiopharmaceuticsandClinicalPharmacokineticsbyMiloGibaldi,4th edition,Philadelphia,LeaandFebiger,1991
2. BiopharmaceuticsandPharmacokinetics,A.Treatise,D.M.BrahmankarandSunilB.Jaiswal., VallabPrakashan,Pitampura,Delhi
3. AppliedBiopharmaceuticsandPharmacokineticsbyShargel.LandYuABC,2ndedition, ConnecticutAppletonCenturyCrofts,1985
4. TextbookofBiopharmaceuticsandPharmacokinetics,Dr.ShobhaRaniR.Hiremath,PrismBook
5. PharmacokineticsbyMiloGibaldiandD.Perrier,2ndedition,MarcelDekkerInc.,NewYork,1982
6. CurrentConceptsinPharmaceuticalSciences:Biopharmaceutics,Swarbrick.J,LeaandFebiger, Philadelphia,1970

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7. ClinicalPharmacokinetics,ConceptsandApplications3rdeditionbyMalcolmRowlandandTho m~ N.Tozer,Lea andFebiger,Philadelphia,1995
8. Dissolution,BioavailabilityandBioequivalence,Abdou.H.M,MackPublishingCompany, Pennsylvania 1989
9. BiopharmaceuticsandClinicalPharmacokinetics,AnIntroduction,4thedition,revisedand expandebyRobert.E.Notari,MarcelDekkerInc,New YorkandBasel,1987.
10. BiopharmaceuticsandRelevantPharmacokineticsbyJohn.GWagnerandM.Pemarowski,1stedit ion,DrugIntelligence Publications,Hamilton,Illinois,1971.
11. EncyclopediaofPharmaceuticalTechnology,Vol13,JamesSwarbrick,James.G.Boylan, MarcelDekkerInc,NewYork,1996.
12. BasicPharmacokinetics,1stedition,SunilSJambhekarandPhilipJBreen,pharmaceutical press,RPSPublishing,2009.
13. AbsorptionandDrugDevelopment- Solubility,Permeability,andChargeState,AlexAvdeef,JohnWiley&Sons,Inc,2003.

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MOLECULAR PHARMACEUTICS
(NANOTECHNOLOGY&TARGETED DDS)(NTDS)
(MPH202T)

THEORY **60Hrs**

Scope

Thiscourseisdesignedtoimpartknowledgeontheareaofadvancesinnoveldrugdeliverysystems.

Objectives

Uponcompletionofthecoursestudentshallbeabletounderstand Thevariousapproach

- esfor
- developmentofnoveldrugdeliverysystems.Thecriteriaforselectionofdrugsandp
- olymersforthedevelopmentofNTDSTheformulationandevaluationofnoveldrug deliverysystems.

UNIT-I **9Hrs**

TargetedDrugDeliverySystems:Concepts,Eventsandbiologicalprocessinvolvedindrug targeting.TumortargetingandBrainspecificdelivery.

UNIT-II **9Hrs**

TargetingMethods:introduction,types,preparationandevaluationofNanoParticles&Liposomes

UNIT-III **9Hrs**

Micro Capsules / Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies;preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes,Electrosomes.

UNIT-IV **9Hrs**

PulmonaryDrugDeliverySystems:Aerosols,propellents,ContainersTypes,preparationandevaluation,Intra NasalRoute Deliverysystems;Types,preparationandevaluation.

UNIT-V **9Hrs**

Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potentialtarget diseases for gene therapy(inherited disorder and cancer).Geneexpression systems (viral and nonviral gene transfer). Liposomal gene delivery systems.Biodistribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules andaptamersas drugs offuture.

UNIT-VI **8Hrs**

Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal andtransdermaldeliveryofvaccines.

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UNIT-VII **7Hrs**

StudyofcommercialformulationsDOXIL,RISPERDALCONSTA,LUPRONDEPOT,INVEGASUSTENNA,andLANCOME.

REFERENCEBOOKS

1. YW.Chien,NovelDrugDeliverySystems,2ndedition,revisedandexpanded,Marcel Dekker,Inc.,New York,1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances,VallabhPrakashan,NewDelhi,Firstedition2002.
3. N.K.Jain,ControlledandNovelDrugDelivery,CBSPublishers&Distributors,NewDelhi,Firstedition1997(reprintin2001).

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PHARMACEUTICALPRODUCTIONTECHNOLOGY
(MPH203T)

THEORY **60HRS**

Scope

Thiscourseisdesigned toimpartknowledge andskillsnecessaryto trainthestudentstobeonparwiththeroutineofIndustrialactivitiesinProduction

Objectives

Oncompletionofthiscourseitisexpectedthatstudentswillbeabletounderstand,H
- andlethe scheduledactivitiesina Pharmaceuticalfirm.
- Managetheproductionoflargebatchesofpharmaceuticalformulations.

UNIT-I **10Hrs**

a) Improved Tablet Production: Tablet production process, unit operation improvements,granulationandpelletizationequipments,continuousandbatchmixing,rapidmixinggranulators,rotagranulators,spheronizersandmarumerisers,andotherspecializedgranulationanddryingequipments.Problemsencountered.

b) CoatingTechnology:Process,equipments,particlecoating,fluidizedbedcoating,applicationtechniques.Problems encountered.

UNIT-II **9Hrs**

ParenteralProduction:Plant layout, design area planning & environmentalcontrol, wallandfloor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilitiesequipmentlocation,engineeringandmaintenance.

UNIT-III **9Hrs**

Lyophilization & Spray drying Technology: Principles,process,freeze-drying and spraydryingequipments.

UNIT-IV **9Hrs**

CapsuleProduction:Productionprocess,advancesincapsulemanufacturingandfillingmachinesforhard andsoftgelatincapsules.Layoutand problemsencountered.

UNIT-V **9Hrs**

Disperse Systems Production: Production processes, applications of mixers, mills, disperseequipmentsincludingfine solids dispersion,problemsencountered.

UNIT-VI **7Hrs**

PackagingTechnology:Typesofpackagingmaterials,machinery(stripandblister),labeling,package printingfordifferentdosageforms.

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UNIT-VII **7Hrs**

AirHandlingSystems:StudyofAHUs,humidity&temperaturecontrol,airfiltrationsystems, dust collectors. Water Treatment Process: Techniques and maintenance – RO, DM,ultra–filtration,WFI.

REFERENCEBOOKS:

1. TheTheory&PracticeofIndustrialPharmacy,L.Lachman,VarghesePubl,Bombay.
2. ModernPharmaceuticsbyBanker,Vol72,MarcelDekker,NY.
3. PharmaceuticalDosageForms,Vol1,2,3byLachman,Lieberman,MarcelDekker,NY.
4. PharmaceuticalDosageForms,Parentralmedications,Vol1,2byK.E.Avis,MarcelDekker,NY.
5. PharmaceuticalProductionFacilities,designandapplications,byG.C.Cole,TaylorandFrancis.
6. DispersedSystemVol1,2,3byLachman,Lieberman,MarcelDekker,NY.
7. Productdesignandtestingofpolymericmaterialsby N.P.Chezerisionoff.
8. PharmaceuticalProjectManagement,T.Kennedy,Vol86,MarcelDekker,NY.
9. PackagingPharmaceuticalandHealthCare,H.Lockhard.
10. QualityControlofPackagingMaterialsinPharmaceuticalIndusty,.Kharburn,MarcelDekker, NY.
11. Freezedrying /LyophilizationofPharmaceuticals&BiologicalProducts,L.Ray,Vol96,MarcelDekker,NY.
12. TabletMachineInstrumentationInPharmaceuticals,PRWatt,EllisHorwoods,UK.

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COSMETICSAND COSMECEUTICALS
(MPH 204T)

THEORY **60Hrs**

Scope

Thiscourseisdesignedtoimpartknowledgeandskillsnecessaryforthefundamentalneedforcosmetic andcosmeceuticalproducts.

Objectives

Uponcompletionofthecourse,thestudentsshallbeabletounderstandKeyi

- ngredientsusedincosmeticsandcosmeceuticals.
- Keybuildingblocksforvariousformulations.Currentte
- chnologiesinthemarket
- Variouskeyingredientsandbasicsciencetodevelopcosmeticsandcosmeceuticals
- Scientificknowledgetodevelopcosmeticsandcosmeceuticalswithdesired Safety,stability,andeffic acy.

UNIT-I **10Hrs**

Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indianregulatoryrequirements for labeling ofcosmetics Regulatoryprovisions relating to import ofcosmetics. Misbranded and spurious cosmetics. Regulatory provisions relating tomanufactureofcosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certaincosmetics,loanlicense,offencesandpenalties.

UNIT-II **10Hrs**

Cosmetics - Biological aspects: Structure of skin relating to problems like dry skin, acne,pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle.Common problems associated with oral cavity. Cleansing and care needs for face, eye lids,lips,hands,feet,nail,scalp,neck,bodyandunder-arm.

UNIT-III **10Hrs**

FormulationBuildingblocks:Buildingblocksfordifferentproductformulationsofcosmetics/cosm eceuticals.Surfactants–Classificationandapplication.Emollients,rheological additives:classification andapplication.Antimicrobial usedas preservatives,their merits and demerits. Factors affecting microbial preservative efficacy. Building blocksforformulationofamoisturizingcream,vanishingcream,coldcream,shampooandtoothpast e.Soaps andsyndetbars.

UNIT-IV **10Hrs**

Perfumes;Classificationofperfumes.Perfumeingredientslistedasallergens inEUregulation.Cont roversialingredients:Parabens,formaldehydeliberators,dioxane.

UNIT-V **10Hrs**

Design of cosmeceutical products: Sun protection, sunscreens classification and regulatoryaspects. Addressing dry skin, acne, pigmentation, prickly heat, wrinkles, body odor,dandruff,dentalcavities,bleedinggums,mouthodorandsensitiveteeththroughcosmeceutical formulations.

UNIT-VI **10Hrs**

Herbal Cosmetics: Herbal ingredients used in Hair care, skin care and oral care. Review ofguidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives,emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulatingherbalcosmetics.

REFERENCEBOOKS

1. Harry'sCosmeticology.8thedition.
2. Poucher'sperfumecosmeticsandSoaps,10thedition.
3. Cosmetics-Formulation,Manufactureandqualitycontrol,PP.Sharma,4th edition
4. HandbookofcosmeticscienceandTechnologyA.O.Barel, M.PayeandH.I.Maibach. 3rdedition
5. CosmeticandToiletriesrecentsupplierscatalogue.
6. CTFAdirectory.

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ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICSPRACTICALS(MPH205P)

1. Improvementofdissolutioncharacteristicsofslightlysolubledrugby Soliddispersiont echnique.
2. Comparisonofdissolutionoftwodifferentmarketedproducts/brands
3. Comparisonofdiffusionstudiesoftwodifferentmarketedproducts/brands
4. Proteinbindingstudiesofahighlyproteinbounddrug&poorlyproteinbounddrug
5. CalculationofallPharmacokineticparametersfromtheI.V.BolusData.
6. CalculationofallPharmacokineticparametersfromtheUrinaryDataofI.V. BolusInjection.
7. CalculationofallPharmacokineticparametersfromtheI.V.InfusionData.
8. CalculationofallPharmacokineticparametersfromtheExtravascularData – ResidualMethod.
9. CalculationofallPharmacokineticparametersfromtheExtravascularData– WagnerNelsonmethod
10. BioavailabilitystudiesofParacetamol(Animal).

PHARMACEUTICS-IIPRACTICALS(MPH206P)

1. Formulationandevaluationoftablets
2. Formulationandevaluationofcapsules
3. Formulationandevaluationofinjections
4. Formulationandevaluationofemulsion
5. Formulationandevaluationofsuspension.
6. Formulationandevaluationofentericcoatingtablets.
7. Preparationandevaluationofafreezedriedformulation.
8. Preparationandevaluationofaspraydriedformulation.
9. Tostudytheeffectoftemperaturechange,nonsolventaddition,incompatiblepolymera dditioninmicrocapsules preparation
10. PreparationandevaluationofAlginatebeads
11. Formulationandevaluationofgelatin/albuminmicrospheres
12. Formulationandevaluationofliposomes/niosomes
13. Formulationandevaluationofspherules
14. ToaddressDryskin,acne,blemish,Wrinkles,bleedinggumsanddandruff
15. FormulationandEvaluationofcosmeticproductspertainingtoskin,hairandteeth.

INDUSTRIALPHARMACY
(MIP)MODERNPHARMACEUTICALANALYTICALTECHNIQUE S(MIP101T)

THEORY **60HOURS**

Scope

This subject deals with various advanced analytical instrumental techniques for identification,characterizationand quantificationofdrugs. Instrumentsdealt are Massspectrometer, IR, HPLC,GC etc.

Objectives

Aftercompletionofcoursestudentisabletoknow,Chemical

- sandExcipients
- Theanalysisofvariousdrugsinsingleandcombinationdosageforms Theoreticalandpractical
- skills oftheinstruments

UNIT-I **10Hrs**

a. UV-Visiblespectroscopy:Introduction,Theory,Laws,InstrumentationassociatedwithUV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visiblespectroscopy.

b. IRspectroscopy:Theory,ModesofMolecularvibrations,Samplehandling,Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affectingvibrationalfrequencies andApplicationsofIR spectroscopy

c. Spectroflourimetry:TheoryofFluorescence,Factorsaffectingfluorescence,Quenchers,Instrumentationand Applicationsoffluorescence spectrophotometer.

UNIT-II **8Hrs**

MassSpectroscopy:Principle,Theory,InstrumentationofMassSpectroscopy,Differenttypesofionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPIAnalyzersof Quadrupole and Time of Flight, Mass fragmentation and its rules,Metastableions,IsotopicpeaksandApplicationsofMassspectroscopy.

UNIT-III **12Hrs**

Chromatography:Principle,apparatus,instrumentation,chromatographicparameters,factorsaffecting resolutionandapplications ofthefollowing:
a)Paperchromatographyb)ThinLayerchromatographyc)Ionexchangechromatographyd)Column chromatography e)Gaschromatography f)HighPerformanceLiquidchromatography g)Affinitychromatography.

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UNIT-IV **12Hrs**

Electrophoresis: Principle, Instrumentation, Working conditions, factorsaffecting separationandapplications of the following:a)Paperelectrophoresisb)Gelelectrophoresisc)Capillaryelectrophoresisd)Zoneelectrophoresise) Movingboundaryelectrophoresisf)Isoelectricfocusing

UNIT-V **10Hrs**

a) Immunologicalassays:RIA(Radioimmunoassay),ELISA,Bioluminescenceassays.
b) Thermaltechniques:DSC,DTA,TGA,Principle,Instrumentation,factorsaffecting,advantages anddisadvantages andPharmaceuticalapplications.

UNIT-VI **8Hrs**

NMRSpectroscopy:Quantum numbersandtheirroleinNMR,Principle,instrumentation,solvent requirements in NMR, Relaxation process, NMR signals in various compounds.Briefoutline ofFT-NMR andC^{13}NMR,applicationsofNMRSpectroscopy.

REFERENCEBOOKS:

1. SpectrometricIdentificationofOrganiccompounds-RobertMSilverstein,Sixthedition,JohnWiley&Sons,2004.
2. PrinciplesofInstrumentalAnalysis -Doglas ASkoog, F. JamesHoller,TimothyA. Nieman,5thedition,Easternpress,Bangalore,1998.
3. Instrumentalmethodsofanalysis–Willards,7thedition,CBSpublishers.
4. PracticalPharmaceuticalChemistry–BeckettandStenlake,VolII,4th edition,CBS Publishers,New Delhi,1997.
5. OrganicSpectroscopy-WilliamKemp,3rdedition,ELBS,1991.
6. QuantitativeAnalysisofDrugs inPharmaceuticalformulation- PDSethi, 3rdEdition,CBSPublishers,NewDelhi,1997.
7. PharmaceuticalAnalysis-Modernmethods–PartB-JWMunson,Volume11,MarcelDekkerSeries

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PHARMACEUTICALFORMULATIONDEVELOPMENT
(MIP102T)

THEORY **60Hrs**

Scope

Thiscourseisdesignedtoimpartknowledgeandskillsnecessarytotrainthestudentsonparwiththeroutine ofIndustrialactivitiesinR&DandF&D.

Objectives

Oncompletionofthiscourse it isexpectedthat studentswillbeableto understand-

- Thescheduledactivitiesina Pharmaceuticalfirm.
- Thepreformulationstudiesofpilot batchesofpharmaceuticalindustry.
- Thesignificance ofdissolutionandproductstability

UNIT-I **10Hrs**

Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphologyandvariations,powderflow,structuremodification,drug-excipientcompatibilitystudies,methodsfordeterminationofincompatability.

UNIT-II **12Hrs**

FormulationAdditives:Studyofdifferentformulationadditives,factorsinfluencingtheirincorporation, role of formulation development and processing, new developments in excipientscience.Designofexperiments–factorialdesignforproductandprocessdevelopment.

UNIT-III **12Hrs**

Solubility:Importance,experimentaldetermination,phasesolubilityanalysis,pH-solubilityprofile, solubilization techniques to improve solubility and utilization of analytical methods –cosolvency, salt formation, complexation, solid state manipulation, micellar solubilization andhydrotropy.

UNIT-IV **12Hrs**

Dissolution: Theories, mechanisms of dissolution, in-vitro dissolution testing models – sink andnon-sinkindissolution.Factorsinfluencingdissolutionandintrinsicdissolutionstudies.Dissolution test apparatus – designs, dissolution testing for conventional and controlled releaseproducts. Data handling and correction factor in dissolution calculation. Biorelevent media, in-vitroandin-vivocorrelations,levelsofcorrelations.

UNIT-V **12Hrs**

ProductStability:Degradationkinetics,mechanisms,stabilitytestingofdrugsandpharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies,interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment.Stabilityprotocols,reports andICHguidelines.

REFERENCEBOOKS:

1. LachmanL,LiebermanHA, KanigJL. TheTheoryandPracticeOfrdIndustrialPharmacy,3ed.,VarghesePublishers,Mumbai1991.th
2. SinkoPJ.Martin'sphysicalpharmacyandpharmaceuticalsciences, 5ed.,B.I.PublicationsPvt.Ltd,Noida,2006.
3. LiebermanHA,LachmanL,SchwartzJB. Pharmaceuticaldosage forms: nd tabletsVol.I-III, 2ed.,CBSPublishers&distributors,New Delhi,2005.
4. ConnersKA.ATextbookofpharmaceuticalanalysiWellsJI.Pharmaceuticalpreformulation:Theph ysicochemicalpropertiesofdrugsubstances.EllisHorwoodLtd.,England,1998.
5. YalkowskySH.Techniquesofsolubilizationofdrugs.Vol-12.MarcelDekkerInc.,New York,1981
6. DressmanJ,KramerJ.Pharmaceuticaldissolutiontesting.Saurahprinterpvt.Ltd.,New Delhi,2005.rd
7. SethiPD.Quantitativeanalysisofdrugsinpharmaceuticalformulations,3ed.,CBS publications,New Delhi,2008.Rd
8. CarstensenJT,RhodesCT.Drugstabilityprinciplesandpractices,3CBSPublishers& distributors,New Delhi,2005.ed.,
9. YoshiokaS, StellaVJ. Stabilityofdrugsanddosageforms, Springer(India) Pvt. Ltd.,NewDelhi,2006.th
10. BankerGS,RhodesCT.ModernPharmaceutics,4Inc,NewYork,2005.
11. W.Grimm-Stabilitytestingofdrugproducts.ed.,MarcelDekker
12. MazzoDJ.Internationalstability testing.EasternPressPvt.Ltd.,Bangalore,1999.13.BeckettAH,Stenlake JB.Practical pharmaceutical th chemistry,Part I& II.,4 2004.ed.,CBSPublishers&distributors,New Delhi,
14. IndianPharmacopoeia.ControllerofPublication.Delhi,1996.
15. BritishPharmacopoeia.BritishPharmacopoeiaCommissionOffice,London,2008.
16. UnitedStatesPharmacopoeia.UnitedStatesPharmacopeialConvention,Inc,USA,2003.
17. EncyclopaediaofPharm.Technology,VolI–III.
18. WellsJ.I.PharmaceuticalPreformulation:Thephysicochemicalpropertiesofdrug substances,EllisHorwoodLtd.England,1988.

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NOVELDRUGDELIVERYSYSTEMS

(MIP103T)

THEORY **60Hrs**

Scope

This course is designed to impart knowledge and skills necessaryto trainthe students inthe area ofnoveldrugdeliverysystems.

Objective

Oncompletionofthiscourseitisexpectedthatstudentswillbeabletounderstand,

- Theneed,concept,designandevaluationofvariouscustomized,sustainedandcontrolled releasedosage forms.
- Toformulateandevaluatevariousnoveldrugdeliverysystems

UNIT-I **10Hrs**

SustainedRelease(SR)andControlledRelease(CR)formulations:Introduction&basic concepts,advantages/disadvantages, factors influencing, Physicochemical & biological approaches forSR/CR formulation, Mechanism of Drug Delivery from SR/CR formulationcomputationofdesiredreleaserateanddoseforcontrolledreleaseDDS,pharmacokinetic designforDDS–intermittent,zeroorder&firstorderrelease.

UNIT-II **8Hrs**

CarriersforDrugDelivery:Polymers/co-polymersintroduction,classification,characterization,polymerizationtechniques,applicationinCDDS/NDDS, biodegradable&naturalpolymers.

UNIT-III **8Hrs**

RateControlledDrugDeliverySystems:Principles&Fundamentals,Types,Activation;ModulatedDrugDeliverySystems;Mechanicallyactivated,pHactivated,Enzymeactivated,andOsmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems;Principles&Fundamentals.

UNIT-IV **8Hrs**

Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oralDDS, GRDDS, Mucoadhesive and buccalDDS, colon specific, liquid sustained release systems,Oculardeliverysystems.

UNIT-V **6Hrs**

Transdermal DrugDelivery Systems:Structure of skinandbarriers,Penetrationenhancers,TransdermalDrugDeliverySystems,Formulationandevaluation.

UNIT-VI **6Hrs**

Protein andPeptideDelivery:Barriersforprotein delivery.Formulation andEvaluation ofdeliverysystems ofproteins andothermacromolecules.

UNIT-VII **10Hrs**

TargetedDrugDeliverySystems: Importance,concept, biologicalprocessandeventsinvolved in drugtargeting,design,formulation&evaluation,methodsindrugtargeting– nanoparticles,liposomes,niosomes,pharmacosomes,resealederythrocytes,microspheres,magnetic microspheres.Specialized pharmaceutical emulsions–multiple emulsions,micro-emulsions.StudyofcommercialformulationsDOXIL,RISPERDALCONSTA,LUPRONDEPOT,IN VEGASUSTENNA,andLANCOME.

UNIT-VIII **6Hrs**

BiotechnologyinDrugDeliverySystems:Briefreviewofmajorareas-recombinantDNAtechnology,monoclonalantibodies,genetherapy.

REFERENCEBOOKS:

1. NovelDrugDeliverySystem,Y.W.Chein,Vol50,MarcelDekker,NY.
2. ControlledDrugDeliverySystems,Robinson,Vol29,MarcelDekker,NY.
3. TransdermalControlledSystemicMedications,YWChein,Vol31,MarcelDekker,NY.
4. BioadhesiveDDS,E.Mathiowitz,Vol98,MarcelDekker,NY.
5. NasalSystemDrugDelivery,K.S.E.Su,Vol39,MarcelDekker,NY.
6. DrugDeliveryDevices,Vol32,PTyleMarcel Dekker,NY.
7. PolymersforControlledDrugDelivery,P.J.Tarcha,CRCPress.
8. PharmaceuticalBiotechnology,Vyas,CBS,Delhi.
9. BiotechnologyofIndustrialAntibiotics,E.J.Vandamme,MarcelDekker,NY.
10. ProteinFormulation&Delivery,E.J.McNally,Vol99,MarcelDekker,NY.
11. DrugTargeting,M.H.Rubinstein,JohnWiley,NY.

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IPR AND REGULATORYAFFAIRS
(MPH104T)

THEORY **60Hrs**

Scope

Course designed toimpartadvanced knowledgeand skills required to learn the concept ofgeneric drug and their development, various regulatory filings in different countries, differentphases of clinical trials and submitting regulatory documents: filing process of IND, NDA andANDA

- Toknowtheapprovalprocessof
- Toknowthechemistry, manufacturingcontrolsandtheirregulatoryimportance
- Tolearnthedocumentationrequirementsfor
- Tolearntheimportanceand

Objectives:

Uponcompletionofthecourse,it isexpectedthat thestudentswillbeableto understand

- TheConceptsofinnovatorandgeneric
- drugs,drugdevelopmentProcessTheRegulatoryguidance'sandguidelinesforfilingandappr
- oval processPreparationofDossiersandtheirsubmissiontoregulatoryagencies indifferent
- countries Postapproval regulatory requirements for actives and drug
- productsSubmissionofglobaldocumentsinCTD/eCTDformatsClinicaltrialsrequirementsf
- orapprovalsforconductingclinicaltrials
- Pharmacovigilenceandprocessofmonitoring inclinicaltrials.

UNIT-I **10Hrs**

Drugproductdevelopment:Activepharmaceuticalingredients,drugmasterfile(DMF)andimpurities. Generic product development: Introduction, Hatch-Waxman act and amendments,GUDUFA, ANDA (505j), ANDA approval process. New drug application (505B1 and 505B2).NDAapprovalprocessincludingIND.Scaleupandpostapprovalchanges(SUPAC).Bioequiva lenceandBioavailability,differenttypesofstudiesfordrugproductapproval.

UNIT-II **10Hrs**

ICH- Guidelines of ICH – Q7 to Q11, M9. Clinical Trials. HIPPA – new, requirements toclinicalstudyprocess,Parmacovigilance safetymonitoringinclinicaltrials.

UNIT-III **10Hrs**

ANDA for generic drugs ways and means of US registration for foreign drugs. CMC, Postapprovalregulatoryaffairs.Regulationforcombinationproducts,medicaldevices&Biosimilars.

UNIT-IV **10Hrs**

BriefintroductiontoCDSCO,WHO,USFDA,EMEA,TGA,MHRA,MCC,ANVISA.

UNIT-V **10Hrs**

Definitions, Need for Patenting, Types of Patents, Conditions to be satisfied by an invention tobePatentable,introduction topatentand patentsearch.Parts of Patent. Filing of patents. Theessentialelementsofpatent. Guidelines for preparationoflaboratorynotebook, Non-obviousness inpatent.

UNIT-VI **10Hrs**

Copyright,Trademark,Geographicalindicationacts,Patentlitigation,180daysmarketexclusivityand Doctrineofequivalents.

REFERENCEBOOKS:

1. GenericDrugProductDevelopment,SolidOralDosageforms,LeonShargeland IsaderKaufer,MarcelDekkerseries,Vol.143
2. ThePharmaceuticalRegulatoryProcess,Second EditionEditedbyIraR.Berryand RobertP.Martin,Drugsandthe PharmaceuticalSciences,Vol.185, InformaHealthcarePublishers.
3. NewDrugApprovalProcess:AcceleratingGlobalRegistrationsByRichardAGuarino, MD,5thedition,Drugs andthePharmaceuticalSciences,Vol.190.
4. Guidebookfordrugregulatorysubmissions/SandyWeinberg.ByJohnWiley&Sons.Inc.
5. FDAregulatoryaffairs:aguideforprescriptiondrugs, medicaldevices,andbiologics/editedByDouglas J.Pisano,DavidMantus.
6. ClinicalTrialsandHumanResearch:APracticalGuidetoRegulatoryComplianceByFayA .RozovskyandRodneyK.Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

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MODERN PHARMACEUTICAL ANALYTICALTECHNIQUES
PRACTICALS (MIP105P)

1. Analysisofpharmacopoeialcompoundsandtheirformulations byUVVisspectrophotometer(Min imum4Experiments)
2. Simultaneousestimationofmulticomponentcontainingformulations byUV/HPLCspectrophoto metry(Minimum4Experiments)
3. ExperimentsbasedonHPLC
4. ExperimentsbasedonGasChromatography
5. Estimationofriboflavin/quininesulphatebyfluorimetry
6. Estimationofsodium/potassiumbyflamephotometry

INDUSTRIALPHARMACY–
IPRACTICALS (MIP106P)

1. Tocarryoutpreformulationstudiesofdrugslikeeffectofsurfactantsandp Honthe solubilityofdrugs,compatibilityevaluationofdrugsandexcipients byDSCandFTIR .
2. Formulationandevaluationof SR/CRTabletsand compareIn-Vitro dissolutionprofileofSR/CRMarketedformulation.

3. Formulationandevaluationosmoticallycontrolled DDS
4. PreparationandevaluationofFloatingDDS-hydrodynamicallybalancedDDS
5. Formulationandevaluationof Mucoadhesivetablets.
6. Formulationandevaluationoftransdermalpatches.
7. Stabilitystudiesofdrugsinsolutionsandsoliddosageformsaccordingtothe ICHguidelines.
8. Tostudytheeffectofcompressionalforce,particlesizeandbindersontabletsdisintegrationtime anddissolutionofatablet.
9. TostudyMicromeriticpropertiesofpowdersandgranulation.
10. Preparationandevaluationofdifferentpolymericmembranes.
11. Tostudytheeffectoftemperaturechange,nonsolventaddition,incompatiblepolymeradditionin microcapsulespreparation
12. PreparationandevaluationofAlginatebeads
13. Formulationandevaluationofgelatin/albuminmicrospheres
14. Formulationandevaluationofliposomes/niosomes

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SEMESTER-II
ADVANCEDBIOPHARMACEUTICS&PHARMACOKINETICS
(MPH201T)

THEORY **60Hrs**

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, doseadjustmentsandtoapplybiopharmaceuticstheoriesinpracticalproblemsolving.Basictheoretical discussions of the principles of biopharmaceutics and pharmacokinetics are providedtohelpthestudents'toclarifytheconcepts.

Objectives

Uponcompletionofthiscourse it isexpectedthatstudentswillbeable understand,

- Thebasicconceptsinbiopharmaceuticsandpharmacokinetics.
- Theuserawdataandderivethepharmacokineticmodelsandparametersthebestdescribetheproces sofdrug absorption,distribution,metabolismandelimination.
- Thecriticalevaluationofbiopharmaceuticstudiesinvolvingdrugproductequivalency.Thedesignandevaluati
- onofdosageregimensofthedrugsusingpharmacokineticand biopharmaceuticparameters.
- Thepotentialclinicalpharmacokineticproblemsandapplicationofbasicsofpharmacokinetic

UNIT-I **10Hrs**

DrugAbsorptionfrom theGastrointestinal Tract: Gastrointestinal tract, Mechanism of drugabsorption,Factorsaffectingdrugabsorption,pH–partitiontheoryofdrugabsorption.Formulationandphysicochemicalfactors:Dissolutionrate,Dissolut ionprocess,Noyes–Whitneyequation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption:role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as adosageform,Capsuleasadosageform,Tabletasadosageform,Dissolutionmethods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data.Transportmodel:Permeability-Solubility-ChargeStateandthepHPartitionHypothesis,Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment,Tight-JunctionComplex.

UNIT-II **10Hrs**

Biopharmaceutic considerations in drug product design and In Vitro Performance: Introduction,biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption,physicochemical nature of the drug, formulation factors affecting drug product performance,

invitro:dissolutionanddrugreleasetesting,compendialmethodsofdissolution,alternativemethods ofdissolutiontesting, meeting dissolutionrequirements, problems of variable controlindissolution testing performance of drug products. In vitro–in vivo correlation, dissolution profilecomparisons.

UNIT-III **10Hrs**

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: onecompartmentmodel-IVbolus,IVinfusion,extra-vascular.Multi compartmentmodel:twocompartment-modelinbrief.

UNIT-IV **10Hrs**

Non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimationofKmaxandVmax.NoncompartmentalPharmacokinetics-statisticalmomenttheoryandphysiological pharmacokinetic model.Altered pharmacokinetics in renal and hepatic diseases.Drug interactions: introduction, the effect ofprotein binding on interactions, the effect oftissue-binding on interactions, cytochrome p450-based drug interactions, and drug interactions linkedtotransporters.10Hrs

UNIT-V **10Hrs**

DrugProductPerformance,InVivo:BioavailabilityandBioequivalence:drugproductperformance, purpose of bioavailability studies, relative and absolute availability. Methods forassessingbioavailability,bioequivalencestudies,designandevaluationofbioequivalencestudies, study designs, crossover study designs, evaluation of the data, bioequivalence example,study submission and drug review process. Biopharmaceutics classification system, methods.Permeability:In-vitro,in-situandIn-vivomethods.genericbiologics(biosimilardrugproducts),clinical significance of bioequivalence studies, special concerns in bioavailability andbioequivalence studies,generic substitution.

UNIT-VI **10Hrs**

Application of Pharmacokinetics: Chrono pharmacokinetics, Modified-Release Drug Products,TargetedDrugDeliverySystemsandBiotechnologicalProducts.IntroductiontoPharmacokineticsandpharmacodynamicsofbiotechnologydrugsProteinsandpeptides,Monoclonalantibodies,Oligonucleotides,Vaccines(immunotherapy),Genetherapies.

REFERENCEBOOKS:

1. BiopharmaceuticsandClinicalPharmacokineticsbyMiloGibaldi,4th edition,Philadelphia,LeaandFebiger,1991
2. BiopharmaceuticsandPharmacokinetics,A.Treatise,D.M.BrahmankarandSunilB.Jaiswal., VallabPrakashan,Pitampura,Delhi
3. AppliedBiopharmaceuticsandPharmacokineticsbyShargel.LandYuABC,2ndedition, ConnecticutAppletonCenturyCrofts,1985
4. TextbookofBiopharmaceuticsandPharmacokinetics,Dr.ShobhaRaniR.Hiremath,PrismBook
5. PharmacokineticsbyMiloGibaldiandD.Perrier,2ndedition,MarcelDekkerInc.,NewYork,1982
6. CurrentConceptsinPharmaceuticalSciences:Biopharmaceutics,Swarbrick.J,LeaandFebiger, Philadelphia,1970

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7. ClinicalPharmacokinetics,ConceptsandApplications3rdeditionbyMalcolmRowlandandTho m~ N.Tozer,Lea andFebiger,Philadelphia,1995
8. Dissolution,BioavailabilityandBioequivalence,Abdou.H.M,MackPublishingCompany, Pennsylvania 1989
9. BiopharmaceuticsandClinicalPharmacokinetics,AnIntroduction,4th edition,revisedand expandebyRobert.E.Notari,MarcelDekkerInc,New YorkandBasel,1987.
10. BiopharmaceuticsandRelevantPharmacokineticsbyJohn.GWagnerandM.Pemarowski,1stedi tion,DrugIntelligence Publications,Hamilton,Illinois,1971.
11. EncyclopediaofPharmaceuticalTechnology,Vol13,JamesSwarbrick,James.G.Boylan, MarcelDekkerInc,NewYork,1996.
12. BasicPharmacokinetics,1stedition,SunilSJambhekarandPhilipJBreen,pharmaceutical press,RPSPublishing,2009.
13. AbsorptionandDrugDevelopment-Solubility,Permeability,andChargeState,AlexAvdeef,JohnWiley&Sons,Inc,2003.

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SCALEUPANDTECHNOLOGYTRANSFER
(MIP202T)

THEORY **60Hrs**

Scope

Thiscourseisdesigned toimpartknowledgeandskillsnecessaryto trainthestudentstobeonscaleup,technologytransferprocess andindustrialsafetyissues.

Objectives:

Oncompletionofthiscourseitisexpectedthatstudentswillbeabletounderstand,M

- anage the scale upprocessinpharmaceuticalindustry.
- Assistintechnologytransfer.
- Toestablishsafetyguidelines,whichpreventindustrialhazards.

UNIT-I **10Hrs**

Pilotplantdesign:Basic requirementsfordesign,facility,equipmentselection,for tablets,capsules, liquid orals, parenteral and semisolid preparations. Scale up: Importance, Technologytransfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquidorals,semisolids,parenteral,NDDSproducts– stressonformula,equipments,productuniformity,stability,rawmaterials,physicallayout,input,in-processandfinishedproductspecifications,problemsencounteredduringtransferoftechnology.12Hrs

UNIT-I **12Hrs**

Validation: General concepts, types, procedures & protocols, documentation, VMF. Analyticalmethodvalidation,cleaningvalidation

UNIT-III **12Hrs**

Equipment Qualification: Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membranefilter,rapid mixergranulator, cone blender, FBD, tablet compression machine, liquid filling andsealingmachine.Aseptic roomvalidation.

UNIT-IV **12Hrs**

Process validation: Importance, validation of mixing, granulation, drying, compression, tabletcoating,liquidfillingandsealing,sterilization,waterprocesssystems,environmentalcontrol.

UNIT-V **12Hrs**

Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical,Monitoring&preventionsystems,industrialeffluenttesting&treatment.Controlofen vironmentalpollution.

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REFERENCEBOOKS:

1. Pharmaceuticalprocessvalidation,JRBerry,Nash,Vol57,MarcelDekker,NY.
2. PharmaceuticalProductionfacilities,designandapplications,byGCCole,TaylorandFrancis.
3. Pharmaceuticalprojectmanagement,T.Kennedy,Vol86,MarcelDekker,NY.
4. Thetheory&PracticeofIndustrialPharmacy,L.Lachman,H.A.Lieberman,nVarghesePubl.Bombay.
5. Tabletmachineinstrumentsinpharmaceuticals,PRWatt,JohnWiloy.
6. Pharmaceuticaldosageforms,Tablets,Vol1,2,3byLachman,Lieberman, MarcelDekker,NY.
7. Pharmaceuticaldosageforms,Parentralmedications, Vol1,2byK.E.Avis, MarcelDekker,NY.
8. DispersedsystemVol1,2,3byLachman,Lieberman,MarcelDekker,NY.
9. Subrahmanyam, CVS, Pharmaceuticalproductionand Management, 2007, VallabhPrakashan,Dehli.

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PHARMACEUTICALPRODUCTIONTECHNOLOGY(MI P203T)

THEORY **60HRS**

Scope

Thiscourseisdesignedtoimpartknowledgeandskillsnecessaryto trainthestudentstobeonparwiththeroutineofIndustrialactivitiesinProduction

Objectives

Oncompletionofthiscourseitisexpectedthatstudentswillbeabletounderstand,H

- andlethe scheduledactivitiesinaPharmaceuticalfirm.
- Managetheproductionoflargebatchesofpharmaceuticalformulations.

UNIT-I **10Hrs**

a) ImprovedTabletProduction:Tabletproductionprocess,unitoperationimprovements,granulation and pelletization equipments, continuous and batch mixing, rapid mixinggranulators,rota granulators, spheronizers and marumerisers, and other specialized granulation and dryingequipments.Problems encountered.

b) CoatingTechnology:Process,equipments,particlecoating,fluidizedbedcoating,applicationte chniques.Problems encountered.

UNIT-II **9Hrs**

ParenteralProduction: Area planning &environmental control, walland floortreatment, fixturesandmachineries,changerooms,personnelflow,utilities&utilitiesequipmentlocation,enginee ringandmaintenance.

UNIT-III **9Hrs**

Lyophilization & Spray drying Technology: Principles, process, freeze-drying and spray dryingequipments.

UNIT-IV **9Hrs**

Capsule Production: Production process, improved capsule manufacturing and filling machinesforhardandsoftgelatincapsules.Layoutandproblemsencountered.

UNIT-V **9Hrs**

DisperseSystemsProduction:Productionprocesses,applicationsofmixers,mills,disperseequipments includingfine solidsdispersion,problemsencountered.

UNIT-VI **7Hrs**

Packaging Technology: Types ofpackaging materials, machinery, labeling, package printing fordifferentdosageforms.

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UNIT-VII **7Hrs**

Air Handling Systems: Study of AHUs, humidity & temperature control, air filtration systems,dustcollectors. WaterTreatmentProcess: Techniques andmaintenance– RO,DM,ultra – filtration,WFI.

REFERENCES

1. TheTheory&PracticeofIndustrialPharmacy,L.Lachman,VarghesePubl,Bombay.
2. ModernPharmaceuticsbyBanker,Vol72,MarcelDekker,NY.
3. PharmaceuticalDosageForms,Vol1,2,3 byLachman,Lieberman,MarcelDekker,NY.
4. PharmaceuticalDosageForms,Parentralmedications,Vol1,2byK.E.Avis,MarcelDekker,NY.
5. PharmaceuticalProductionFacilities,designandapplications,byG.C.Cole,TaylorandFrancis.
6. DispersedSystemVol1,2,3byLachman,Lieberman,MarcelDekker,NY.
7. Productdesignandtestingofpolymericmaterialsby N.P.Chezerisionoff.
8. PharmaceuticalProjectManagement,T.Kennedy,Vol86,MarcelDekker,NY.
9. PackagingPharmaceuticalandHealthCare,H.Lockhard.
10. QualityControlofPackagingMaterialsinPharmaceuticalIndusty,.Kharburn,Marcel Dekker,NY.
11. Freezedrying /LyophilizationofPharmaceuticals&BiologicalProducts,L.Ray,Vol96,MarcelDekker,NY.
12. TabletMachineInstrumentationInPharmaceuticals,PRWatt,EllisHorwoods,UK.

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ENTREPRENEURSHIPMANAGEMENT(MIP204T)

THEORY **60Hrs**

Scope: Thiscourseisdesignedtoimpartknowledgeandskillsnecessarytotrainthestudentsonentreprene urship management.

Objectives:

Oncompletionofthiscourseitisexpectedthatstudentswillbeabletounderstand,TheRo

- le ofenterpriseinnationalandglobaleconomy
- Dynamics of motivation and concepts of
- entrepreneurshipDemandsandchallengesofGrowthStrategiesAndNetworking

UNIT-I **12Hrs**

Conceptual Frame Work: Concept need and process in entrepreneurship development. Role ofenterpriseinnationalandglobaleconomy.Typesofenterprise–MeritsandDemerits.Government policies and schemes for enterprise development. Institutional support in enterprisedevelopmentandmanagement.

UNIT-II **12Hrs**

Entrepreneur: Entrepreneurial motivation – dynamicsofmotivation. Entrepreneurialcompetency – Concepts.DevelopingEntrepreneurialcompetencies-requirementsandunderstandingtheprocessofentrepreneurshipdevelopment,self-awareness,interpersonalskills,creativity,assertiveness,achievement,factors affectingentrepreneurrole.

UNIT-III **12Hrs**

LaunchingAndOrganisingAnEnterprise:Environmentscanning–Information,sources,schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibilitystudy, SWOT Analysis. Resource mobilisation - finance, technology, raw material, site andmanpower. Costing and marketing management and quality control. Feedback, monitoring andevaluation.

UNIT-IV **12Hrs**

Growth Strategies And Networking: Performance appraisal and assessment. Profitability andcontrol measures, demands and challenges. Need for diversification. Future Growth – Techniquesofexpansionanddiversification,visionstrategies.Conceptanddynamics.Methods,Jointve nture,co-ordinationandfeasibilitystudy.

UNIT-V **12Hrs**

PreparingProjectProposalToStartOnNewEnterpriseProjectwork–Feasibility report;Planning,resource mobilizationandimplementation.

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REFERENCES

1. Akhauri,M.M.P.(1990):EntrepreneurshipforWomeninIndia,NIESBUD,NewDelhi.
2. Hisrich,R.D&Brush,C.G.(1996)TheWomenEntrepreneurs,D.C.Health&Co.,Toranto.
3. Hisrich,R.D.andPeters,M.P.(1995):Entrepreneurship– Starting,DevelopingandManagingaNew Enterprise,RichardD.,Inwin,INC,USA.
4. Meredith,G.G.etal(1982):PracticeofEntrepreneurship,ILO,Geneva.
5. Patel,V.C.(1987):WomenEntrepreneurship – DevelopingNewEntrepreneurs,AhmedabadEDII.

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PRACTICALS SEM– IIADVANCEDBIOPHARMACEUTICSANDPHARMACOKINETICSPRACTICALS(MIP205P)

1. Improvementofdissolutioncharacteristicsofslightly solubledrugbySoliddispersiontechnique.
2. Comparisonofdissolutionoftwodifferentmarketedproducts/brands
3. Comparisonofdiffusionstudiesoftwodifferentmarketedproducts/brands
4. Proteinbindingstudiesofahighlyproteinbounddrug&poorlyproteinbounddrug
5. CalculationofallPharmacokineticparametersfromtheI.V.BolusData.
6. CalculationofallPharmacokineticparametersfromtheUrinaryDataofI.V.BolusInjection.
7. CalculationofallPharmacokineticparametersfromtheI.V.InfusionData.
8. CalculationofallPharmacokineticparametersfromtheExtravascularData–ResidualMethod.
9. CalculationofallPharmacokineticparametersfromtheExtravascularData–WagnerNelsonmethod
10. BioavailabilitystudiesofParacetamol(Animal).

INDUSTRIALPHARAMCY-IIPRACTICALS(MIP206P)

1. Formulationandevaluationoftablets
2. .Formulationandevaluationofcapsules
3. Formulationandevaluationofinjections
4. Formulationandevaluationofemulsion
5. .Formulationandevaluationofsuspension.
6. Formulationandevaluationofentericcoatingtablets.
7. Preparationandevaluationofafreezedriedformulation.
8. Preparationandevaluationofaspraydriedformulation.
9. ValidationofRotarytabletmachine.
10. ValidationofCoatingpan.
11. Validationoftraydryer.
12. ValidationofAutoclaveandasepticroom.
13.

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PHARMACEUTICAL QUALITY ASSURANCE(MQA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MQA

101T)THEORY **60Hrs**

Scope

Thissubjectdealswithvariousadvancedanalyticalinstrumentaltechniquesforidentification,characterizationandquantificationofdrugs.Instrumentsdealt areNMR,Massspectrometer,IR,HPLC,GC etc.

Objectives

Aftercompletionofcoursestudentisabletoknowaboutchemicalsandexcipients

- Theanalysisofvariousdrugsinsingleandcombinationdosageforms Theoreticala
- ndpracticalskills oftheinstruments

UNIT-I **10Hrs**

a) UV-Visiblespectroscopy:Introduction,Theory,Laws,InstrumentationassociatedwithUV-Visiblespectroscopy,Choiceofsolventsandsolvent effectandApplicationsofUV-Visible spectroscopy,Difference/Derivative spectroscopy.

b) IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling,InstrumentationofDispersiveandFourier-TransformIRSpectrometer,Factorsaffectingvibrationalfrequencies andApplicationsof IRspectroscopy, DataInterpretation.

c) Spectroflourimetry: Theory ofFluorescence, Factorsaffectingfluorescence(Characterestics of drugs that can be analysed by flourimetry), Quenchers,InstrumentationandApplicationsoffluorescence spectrophotometer.

d) Flameemissionspectroscopyand Atomicabsorptionspectroscopy:Principle, Instrumentation,InterferencesandApplications.

UNIT-II **10Hrs**

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation,SolventrequirementinNMR,Relaxationprocess,NMRsignalsinvariouscompounds,Chemicalshift,Factorsinfluencingchemicalshift,Spin-Spincoupling,Couplingconstant,Nuclearmagneticdouble resonance, Briefoutline ofprinciples ofFT-NMR and 13C NMR. Applications of NMRspectroscopy.

UNIT-III **10Hrs**

MassSpectroscopy:Principle,Theory,InstrumentationofMassSpectroscopy,Differenttypesofionization likeelectronimpact,chemical, field,FABandMALDI,APCI,ESI,APPIAnalyzersofQuadrupoleandTimeofFlight,Massfragmentation anditsrules,Metastableions,Isotopicpeaks andApplicationsofMass spectroscopy.

UNIT-IV **10Hrs**

Chromatography:Principle,apparatus,instrumentation,chromatographicparameters,factorsaffectingresolution, isolationofdrugfromexcipients,data interpretationandapplicationsofthefollowing:

- ThinLayerchromatography
- HighPerformance

ThinLayerChromatographyIonexchangechrom

atography

- Columnchromatography
- Gaschromatography
- High Performance Liquid

chromatographyUltraHighPerformanceLiquidchro

matography

Affinitychromatography

- GelChromatography

UNIT-V **10Hrs**

a) Electrophoresis:Principle,Instrumentation,Workingconditions, factors affecting separationandapplicationsofthefollowing:
b) Paperelectrophoresisb)Gelelectrophoresisc)Capillaryelectrophoresisd)Zoneelectrophoresis e)Movingboundaryelectrophoresisf)Isoelectricfocusing
c) XrayCrystallography:ProductionofXrays,DifferentXray
d) methods,Bragg'slaw,Rotatingcrystaltechnique,Xraypowdertechnique,Typesofcrystalsandapplicationsof X-raydiffraction.

UNIT-VI **10Hrs**

a. Potentiometry:Principle,working,IonselectiveElectrodesandApplicationofpotentiometry.
b. Thermal Techniques: Principle, thermal transitions and

Instrumentation(Heatfluxandpower-

compensationanddesigns),ModulatedDSC,HyperDSC,experimentalparameters

(sample preparation, experimental conditions, calibration, heating and cooling rates, resolution,sourceoferrors)andtheir

influence,advantageanddisadvantages,pharmaceuticalapplications.Differential ThermalAnalysis (DTA):Principle, instrumentation andadvantageand disadvantages,pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA:

Principle,instrumentation,factorsaffectingresults,advantageanddisadvantages,pharmaceuticalapplications.

REFERENCEBOOKS:

1. SpectrometricIdentificationofOrganiccompounds-RobertMSilverstein,Sixthedition,JohnWiley&Sons,2004.
2. Principlesof InstrumentalAnalysis-DoglasASkoog,F.JamesHoller,TimothyA.Nieman,5th edition,Easternpress,Bangalore,1998.
3. Instrumentalmethodsofanalysis–Willards,7thedition,CBSpublishers.

4. PracticalPharmaceuticalChemistry–
BeckettandStenlake,VolII,4thedition,CBSPublishers,NewDelhi,1997.
5. OrganicSpectroscopy-WilliamKemp,3rdedition,ELBS,1991.
6. QuantitativeAnalysisofDrugsinPharmaceuticalformulation-
PDSethi,3rdEdition,CBSPublishers,NewDelhi,1997.
7. PharmaceuticalAnalysis-ModernMethods–PartB-JWMunson,Vol11,Marcel.DekkerSeries
8. SpectroscopyofOrganicCompounds,2nd edn.,P.S/Kalsi,WileyesternLtd.,Delhi.
9. TextbookofPharmaceuticalAnalysis,KA.Connors,3rdEdition,JohnWiley&Sons,1982.
10. TextbookofPharmaceuticalAnalysis,KA.Connors,3rdEdition,JohnWiley&Sons,1982.

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QUALITY MANAGEMENT SYSTEMS(MQA102T)

THEORY **60Hrs**

Scope

Thiscourseisdesignedto impart fundamentalknowledgeandconceptsabout variousqualitymanagementprinciplesandsystemsutilizedinthemanufacturingindustry.It alsoaidsinunderstandingthe qualityevaluationinthepharmaceuticalindustries.

Objectives

At completionofthiscourse it isexpectedthatstudentswillbeabletounderstand-

- Theimportance ofquality
- ISOmanagementsystemsToolsforqua
- lityimprovementAnalysisofissuesinq
- uality
- Quality evaluation of
- pharmaceuticalsStabilitytestingofdrugandd
- rugsubstancesStatisticalapproachesforquali ty

Unit-1:

Introduction to Quality: Evolution of Quality, Definition of Quality, Dimensions of QualityQuality as a Strategic Decision: Meaning of strategy and strategic quality management, missionand vision statements, quality policy, Quality objectives, strategic planning and implementation,McKinsey7smodel,Competitiveanalysis,Managementcommitmentto quality CustomerFocus:Meaningofcustomerandcustomerfocus,Classificationofcustomers,Customerfocus ,Customerperceptionofquality,Factorsaffectingcustomerperception,Customer requirements, Meeting customer needs and expectations, Customer satisfaction andCustomer delight, Handling customer complaints, Understanding customer behavior, concept ofinternal and external customers. Case studiesCost of Quality: Cost of quality, Categories of costofQuality,Modelsofcostofquality,Optimisingcosts,Preventingcostofquality 10Hrs

Unit-2. PharmaceuticalqualityManagement:Basicsof QualityManagement,Total QualityManagement (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004,Pharmaceutical Quality Management– ICH Q10, Knowledge management, Quality Metrics,OperationalExcellenceandQualityManagementReview.OSHASguidelines,NABLcertific ationandaccreditation,CFR-21part11,WHO-GMPrequirements. 10Hrs

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Unit-3: Six System Inspection model: Quality Management system, Production system, Facilityand Equipment system, Laboratory control system, Materials system, Packaging and labelingsystem.Conceptofselfinspection.
Qualitysystems:ChangeManagement/Changecontrol.
Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation andhandling,Investigationanddeterminationofrootcause,Corrective&PreventiveActions(CAPA),Returns and Recalls,Vendor Qualification,Annual Product Reviews,Batch ReviewandBatchRelease. ConceptofIPQC, areaclearance/Lineclearance. 10Hrs

Unit-4. Drug Stability: ICH guidelines for stability testing ofdrug substances and drug products.StudyofICHQ8,QualitybyDesignandProcessdevelopmentreport
Qualityriskmanagement:Introduction,riskassessment,riskcontrol,riskreview,riskmanagementtools, HACCP, riskrankingandfilteringaccordingtoICHQ9guidelines.10Hrs

Unit-5. StatisticalProcesscontrol(SPC):DefinitionandImportanceofSPC,Qualitymeasurementinmanufacturing,Statisticalcontrolcharts-conceptsandgeneralaspects,Advantages of statistical control, Process capability, Estimating Inherent or potential capabilityfrom a control chart analysis, Measuring process control and quality improvement, Pursuit ofdecreasedprocess variability.
10Hrs

Unit-6. RegulatoryCompliancethroughQualityManagementanddevelopmentofQualityCultureBenchmarking:Definitionofbenchmarking,Reasonsforbenchmarking,TypesofBenchmarking,Benchmarking process,Advantagesofbenchmarking,Limitationsofbenchmarking 10Hrs

REFERENCEBOOKS:

1. ImplementingJuran'sRoadMapforQualityLeadership:BenchmarksandResults,ByAl Endres,Wiley,2000
2. Understanding,ManagingandImplementingQuality:Frameworks,Techniquesand Cases,ByJijuAntony;DavidPreece,Routledge,2002
3. OrganizingforHighPerformance:EmployeeInvolvement,TQM,Reengineering,andKnowledgeManagementintheFortune1000:TheCEOReportByEdwardE.Lawler;SusanAlbersMohrman;George Benson,Jossey-Bass,2001
4. CorporateCultureandtheQualityOrganizationByJamesW. Fairfield- Sonn, QuorumBooks,2001
5. TheQualityManagementSourcebook:AnInternationalGuidetoMaterialsand ResourcesByChristineAvery;DianeZabel,Routledge,1997
6. TheQualityToolbox,SecondEdition,NancyR. Tague,ASQPublications
7. Juran'sQualityHandbook,SixthEdition,JosephM.JuranandJosephA.DeFeo,ASQ Publications
8. RootCauseAnalysis,TheCoreofProblemSolvingandCorrectiveAction,DukeOkes, 2009,ASQPublications.

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QUALITY CONTROL AND QUALITY ASSURANCE

(MQA103T)THEORY **60Hrs**

Scope

This course deals with the various aspects of quality control and quality assurance aspects ofpharmaceuticalindustries.Itcoverstheimportantaspectslikec GMP,QCtests,documentation, qualitycertifications,GLPandregulatoryaffairs.

Objectives

Upon completion of this course the student should be able

- toUnderstandthecGMPaspectsinapharmaceuticalindustry
- Toappreciate theimportance ofdocumentation
- Tounderstandthescopeofqualitycertificationsapplicableto Pharmaceuticalindustries
- Tounderstandtheresponsibilities ofQA&QC departments.

Unit-1: **12Hrs**

Introduction:Concept and evolution and scopes of Quality Control and Quality Assurance,GoodLaboratoryPractice,GMP,OverviewofICHGuidelines-QSEM,withspecialemphasisonQ-seriesguidelines.

GoodLaboratoryPractices:ScopeofGLP,Definitions, Qualityassuranceunit, protocolforconductofnonclinicaltesting,controlonanimalhouse,reportpreparationanddocumentation. CPCSEAguidelines.

Unit-2: **12Hrs**

cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER)PharmaceuticalInspectionConvention(PIC),WHOandEMEAcovering:Organizationandpersonnelresponsibilities,training,hygieneandpersonalrecords,drugindustrylocation,design,construction and plant lay out, maintenance, sanitation, environmental control, utilities andmaintenanceofsterileareas,controlofcontaminationand Good Warehousing Practice.

Unit-3: **10Hrs**

Analysis of raw materials, finished products, packaging materials, in process quality control(IPQC),Developingspecification(ICHQ6andQ3),purchasespecificationsandmaintenanceof stores for raw materials.In process quality control and finished products quality control forfollowingdosage formsinPharma industryaccordingtoIndian,USandBritishpharmacopoeias:tablets,capsules,ointments, suppositories,creams, parenterals,ophthalmicandsurgicalproducts(Howtoreferpharmacopoeias).

Unit-4: **12Hrs**

Documentationinpharmaceuticalindustry:Threetierdocumentation,Policy,ProceduresandWork instructions, and records (Formats), Basic principles- How to maintain, retention andretrieval etc. Standard operating procedures (How to write), Master Batch Record, BatchManufacturing Record, Quality audit plan and reports. Specification and test procedures,Protocolsandreports.Distributionrecords.Electronicdatahandling.Conceptsofcontrolleddanduncontrolleddocuments Submissiondocumentsforregulators DMFs,asCommonTechnicalDocumentandElectronicCommon Technical Documentation (CTD, eCTD). Concept of regulated and non regulatedmarkets.

Unit-5: **12Hrs**

Manufacturingoperationsandcontrols:Sanitationofmanufacturingpremises,mix-upsandcrosscontamination, processing of intermediates and bulk products, packaging operations, IPQC,release of finished product, process deviations, charge-in of components, time limitations onproduction, drug product inspection, expiry date calculation, calculation of yields, productionrecordreview,changecontrol,sterileproducts,asepticprocesscontrol,packaging,reprocessing,salvaging,handlingofwasteandscrapdisposal.

Introduction,scopeand importanceofintellectualpropertyrights.Conceptoftrademark, copyrightandpatents.

REFERENCEBOOKS:

1. QualityAssuranceGuidebyorganizationofPharmaceuticalProceduresofIndia, 3rdrevisededition,Volume I &II,Mumbai,1996.
2. GoodLaboratoryPracticeRegulations,2ndEdition,SandyWeinbergVol.69,MarcelDekker Series,1995.
3. QualityAssuranceofPharmaceuticals-AcompediumofGuidelinesandRelatedmaterialsVolI&II,2ndedition,WHOPublications,1999.
4. HowtoPracticeGMP's–PPSharma,VandanaPublications,Agra,1991
5. TheInternationalPharmacopoeia –volI,II,III,IV&V-GeneralMethodsofAnalysisandQualityspecification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO,Geneva,2005.
6. GoodlaboratoryPracticeRegulations–AllenF.Hirsch,Volume38,MarcelDekkerSeries,1989.
7. ICHguidelines
8. ISO9000andtotalqualitymanagement
9. Thedrugsandcosmeticsact1940–Deshpande,NileshGandhi,4thedition,SusmitPublishers,2006.
10. QAManual–D.H.Shah,1stedition,BusinessHorizons,2000.
11. GoodManufacturingPracticesforPharmaceuticals a planfor total qualitycontrol –Sidney H. Willig,Vol.52,3rdedition,MarcelDekkerSeries.
12. SteinbornL.GMP/ISOQualityAuditManualforHealthcareManufacturersandTheirSuppliers,SixthEdition,(Volume1-WithChecklistsandSoftwarePackage).Taylor&Francis;2003.
13. Sarker DK. Quality Systems andControlsforPharmaceuticals.John Wiley &Sons;2008.
14. PackagingofPharmaceuticals.
15. ScheduleMandSchedu

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PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA

104T)THEORY **60Hrs**

Scope

Thisdealwithtechnologytransfer coverstheactivitiesassociated withDrugSubstance,DrugProductandanalyticaltestsandmethods,requiredfollowingcandidatedrugselectiontocompletion of technology transfer from R&D to the first receiving site and technologytransferrelatedtopost-marketingchangesinmanufacturing places.

Objectives

Uponcompletionofthiscoursethestudentshouldbeabletountersta

- nd thenewproduct developmentprocess
- Tounderstandthenecessaryinformationtotransfertechnologyfrom R&Dto actualmanufacturingbysorting outvariousinformationobtained during R&D
- Toelucidatenecessaryinformationtotransfertechnologyofexistingproductsbetween variousmanufacturingplaces

Unit-1: **12Hrs**

Principles ofDrugdiscovery and development: Introduction, Clinical research process.Development and informational content for Investigational New Drugs Application (IND),New Drug Application (NDA), Abbreviated New Drug Application (ANDA), SupplementalNewDrugApplication(SNDA),ScaleUpPostApprovalChanges(SUPAC)andBulkactivechemical Post approval changes (BACPAC), Post marketing surveillance, Productregistrationguidelines–CDSCO,USFDA.

Unit-2: **12Hrs**

Pre-formulation studies: Introduction/concept,organoleptic properties, purity, impurityprofiles,particlesize,shapeandsurfacearea.Solubility,Methods toimprovesolubilityof Drugs:Surfactants&itsimportance,co-solvency.TechniquesforthestudyofCrystalpropertiesandpolymorphism.Pre-formulationprotocol, Stabilitytestingduringproductdevelopment.

Unit-3: **12Hrs**

Pilotplantscaleup:Concept, Significance, design,layoutofpilotplantscaleupstudy,operations,largescalemanufacturingtechniques(formula,equipment,process,stabilityand qualitycontrol) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products:opportunitiesandchallenges.

Unit-4: **12Hrs**

Pharmaceuticalpackaging:Pharmaceuticaldosageformandtheirpackagingrequirments,Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packagingsystems,Containerclosuresystems,Issuesfacing moderndrugpackaging,SelectionandevaluationofPharmaceuticalpackagingmaterials.
Qualitycontroltest:Containers,closuresandsecondarypackingmaterials.

Unit-5: **12Hrs**

Technologytransfer:DevelopmentoftechnologybyR&D,

Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitativetechnology models. Documentation in technology transfer: Development report, technology transfer planandExhibit.

REFERENCEBOOKS:

1. Theprocessofnewdrugdiscoveryand development.Iand IIEdition(2006)byCharlesG.Smith, JamesTandO.Donnell. CRCPress,GroupofTaylorandFrancis.
2. LeonLacLachman,Herbert A.Liberman,TheoryandPracticeofIndustrialPharmacy.MarcelDekkerInc. NewYork.
3. SidneyHWilling,MurrayM,Tuckerman.WilliamsHitchingsIV,Goodmanufacturingof pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishinghouse Mumbai.
4. TabletsVol.I,II,IIIbyLeonLachman,HerbertA.Liberman,JosephB.Schwartz,2ndEdn.(1989)MarcelDekkerInc.NewYork.
5. Text bookofBio- PharmaceuticsandclinicalPharmacokineticsbyMilo Gibaldi, 3rdEdn, Lea&Febriger,Philadelphia.
6. Pharmaceuticalproductdevelopment.VandanaV.Patrevale.JohnI.Disouza.Maharukh T.Rustomji.CRC Press,GroupofTaylorandFrancis.
7. Dissolution,BioavailabilityandBio-EquivalencebyAbdouH.M,MackPublishing company,EasternPennsylvania.
8. RemingtonsPharmaceuticalSciences,byAlfonso&Gennaro,19thEdn.(1995)OO2C Lippincott;WilliamsandWilkinsAWoltersKluwer Company, Philadelphia.
9. ThePharmaceuticalSciences;thePharmaPathway'PureandappliedPharmacy' byD.ASawant,PragathiBooksPvt.Ltd.
10. PharmaceuticalPackagingtechnologybyD.A.Dean.E.R.Evans,I.H.Hall.1st Edition(Reprint2006).TaylorandFrancis.LondonandNewYork.

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MODERNPHARMACEUTICALANALYTICALTECHNIQUES(MQA105P)PRACTICALS

ModernPharmaceuticalAnalyticalTechniques

1. AnalysisofPharmacopoeialcompoundsinbulkandintheirformulations(tablet/ capsules/semisolids)byUV Vis spectrophotometer
2. Simultaneousestimationofmulti-drugcomponentcontainingformulationsbyUV spectrophotometry
3. Ascending&radialpaperchromatography
4. Thinlayerchromatography
5. DeterminationoffunctionalgroupsbyFT-IR
6. EffectOfConcentrationOnViscosity
7. ExperimentsbasedonHPLC
8. ExperimentsbasedonGasChromatography
9. Estimationofriboflavin/quininesulphatebyfluorimetry
10. DeterminationofQuenchingeffectofQuininesulphatebypotassiumiodidesolutionbyF luorometry
11. Estimationofsodium/potassiumbyflame photometryorAAS
12. Potentiometrictitrationofstrongacidandstrongbase
13. DeterminationofPkaandLogpofdrugs.
14. Determinationofflowpropertiesandrheologicalbehaviorofsemi-solidorliquid formulations
15. Determinationofbioavailabilityofpoorlysolubledrugsusingsoliddispersiont echnique

QUALITYCONTROLANDQUALITYASSURANCE

(MQA106P)

1. PreparationandIn-processqualitycontroltestforimmediatereleasedtablets
2. Developmentofstabilitystudyprotocol
3. Estimationofprocesscapability
4. Assayofrawmaterialsasperofficialmonographs
5. Testingofrelatedandforeignsubstancesindrugsandrawmaterials
6. Tocarryoutpreformulationstudyfortablets,parenterals(2experiments).
7. Tostudytheeffectofp Honthesolubilityofdrugs
8. QualitycontroltestsforPrimaryandsecondarypackagingmaterials
9. Acceleratedstabilitystudies(1experiment)
10. Improvedsolubilityofdrugsusingsurfactantsystems(1experiment)
11. Improvedsolubilityofdrugsusingco-solvencymethod(1experiment)
12. Investigatingthecompatibilityofdrugsubstanceswithdifferentexcipientstoidentify potentialinteractions ordegradation.
13. Determiningthesolubilityofadrugsubstance invarioussolventsorexcipientstoidentifysuitableformulationsand enhancebioavailability.
14. Developingandtestingdifferentformulationswithvaryingexcipientcompositions, concentrations,anddosageformstoidentifythemostsuitableformulation.
15. Optimizing the manufacturing process parameters (such as blending time,compressionforce,dryingtemperature,orcoatingconditions,toachievede sired productattributes, suchasuniformity, contentuniformity, andstability).
16. Casestudieson,
    - TotalQualityManagement
    - Sixsigma
    - ChangeManagement/Changecontrol.Deviations
    - OutofSpecifications(OOS)
    - OutofTrend(OOT)
    - Corrective&PreventiveActions(CAPA)
    - Deviations

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SEMESTER-II

HAZARDS AND SAFETYMANAGEMENT(MQA201T)

THEORY **60Hours**

Scope

Thiscourseisdesignedtoconveytheknowledgenecessarytounderstandissuesrelatedtodifferent kinds of hazard and their management. Basic theoretical and practicaldiscussions integrate the proficiency to handle the emergency situation in thepharmaceuticalproductdevelopmentprocessandprovidestheprinciplebasedapproachtosolvethecomplextribulations.

Objectives

Atcompletionofthiscourseitisexpectedthatstudentswillbeableto

- Understandaboutenvironmentalproblems amonglearners.
- Impartbasicknowledgeabouttheenvironmentanditsalliedproblems.Devel
- opanattitudeofconcernfortheindustryenvironment.
- Ensuresafetystandardsinpharmaceuticalindustry Providecomprehensiveknowled
- geonthesafetymanagement Empoweranideastoclearmechanismandmanagementi
- ndifferentkindsofhazard

managementsystem Teachthemethodof Hazardassessment,procedure,methodologyforprovid
esafeindustrial
atmosphere

Unit-1: **12Hrs**

Multidisciplinarynatureofenvironmentalstudies: NaturalResources, Renewableandnon-renewable resources,Naturalresourcesandassociatedproblems,

a)Forestresources;b)Waterresources;c)Mineralresources;d)Energyresources;e)Landresources

Ecosystems:ConceptofanecosystemandStructureandfunctionofanecosystem.Environmentalhazards: HazardsbasedonAir, Water,SoilandRadioisotopes.

Unit-2: **12Hrs**

Airbasedhazards:Sources,TypesofHazards,Aircirculationmaintenanceindustryforsterileareaandnon sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention,typesoffire extinguishers andcriticalHazardmanagementsystem.

Unit-3: **12Hrs**

Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis,sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards,Managementofcombustiblegases, ToxicgasesandOxygendisplacinggases management,Regulationsforchemicalhazard,Managementofover-ExposuretochemicalsandTLVconcept

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Unit-4: **12Hrs**

Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanicalelectrical,thermalandprocesshazards.Safetyandhazardsregulations,Fireprotectionsyste m:Fireprevention,typesoffireextinguishersandcriticalHazard management systemmechanicalandchemicalexplosion, multiphasereactions,transporteffectsandglobalrates.Preventiveandprotective management from fires and explosion- electricity passivation, ventilation, andsprinkling,proofing,reliefsystems-reliefvalves,flares,scrubbers.

Unit-5: **12Hrs**

Hazard andriskmanagement:Self-protective measures against workplace hazards. Critical trainingforriskmanagement,ProcessofhazardmanagementICHguidelinesonriskassessmentandRiskman agementmethodsandToolsFactoryactandrules,fundamentalsofaccidentprevention,elementsofsafet yprogrammeandsafetymanagement,Physicochemicalmeasurementsofeffluents,BOD,COD,Determ inationofsomecontaminants,Effluenttreatmentprocedure,Roleofemergencyservices.

REFERENCEBOOKS:

1. Y.K.Sing,EnvironmentalScience,NewAgeInternationalPvt,Publishers,Bangalore
2. "QuantitativeRiskAssessmentinChemicalProcessIndustries"AmericanInstituteofChemicalI ndustries,CentreforChemicalProcesssafety.
3. BharuchaErach,TheBiodiversityofIndia,MapinPublishingPvt.Ltd.,Ahmedabad--380013,India,
4. HazardousChemicals:SafetyManagementandGlobalRegulations,T.S.S.Dikshith,CRCpress

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PHARMACEUTICAL VALIDATION(MQA202T)

THEORY **60Hours**

Scope

The mainpurposeofthesubjectistounderstandaboutvalidationandhowitcanbeappliedtoindustryandthus improvethequalityoftheproducts.Thesubject coversthecompleteinformationaboutvalidation,types,methodologyandapplication.

Objectives

At completionofthiscourse,it isexpectedthatstudentswillbeabletounderstand

- Theconcepts of calibration, qualification and
- validationThequalificationofvariousequipmentsandinstruments
- Process validation of different dosage
- formsValidationofanalyticalmethodforestimationof drugs
- Cleaningvalidationofequipmentsemployedinthemanufactureofpharmaceuticals

Unit-1: **10Hrs**

Introduction to validation: Definition of Calibration, Qualification and Validation, Scope,frequencyandimportance.Differencebetweencalibrationandvalidation.Calibrationofweights andmeasures. Advantages of Validation, scope of Validation, Organization for Validation,ValidationMaster plan, Types ofValidation, Streamlining ofqualification&ValidationprocessandValidationMasterPlan.

Qualification: User requirement specification, Designqualification,FactoryAcceptanceTest(FAT)/SiteAcceptanceTest(SAT),Installationqualification,Operational qualification, Performance qualification, Re-Qualification (Maintaining status-CalibrationPreventive Maintenance,Changemanagement).

Unit-2: **10Hrs**

Qualificationofmanufacturingequipment:DryPowder Mixers, Fluid Bed and Traydryers,TabletCompression(Machine),Dryheatsterilization/Tunnels,Autoclaves,Membranefiltration,Capsulefillingmachine.

Qualificationofanalyticalinstruments:UV-Visiblespectrophotometer,FTIR,DSC,GC, HPLC,HPTLC,LC-MS.

Unit-3: **10Hrs**

Qualificationoflaboratoryequipments:Hardnesstester, Friabilitytest apparatus,tapdensity tester,Disintegration tester, Dissolution test apparatus Validation of Utility systems: Pharmaceuticalwatersystem&pure steam,HVACsystem,Compressedairandnitrogen.

Unit-4: **10Hrs**

ProcessValidation:Concept,Processanddocumentationofprocess Validation.Prospective,Concurrent& Retrospective Validation,Revalidation criteria,Process Validationofvarious formulations (Coated tablets,Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDAguidelinesonProcessValidation-Alifecycleapproach.

Analyticalmethodvalidation:Generalprinciples,Validationofanalyticalmethodasper ICHguidelinesandUSP.

Unit-5: **10Hrs**

CleaningValidation:CleaningMethoddevelopment,Validationofanalyticalmethodusedin cleaning,CleaningofEquipment,CleaningofFacilities.Cleaninginplace(CIP). Validationof facilities in sterile and non-sterileplant.Computerizedsystemvalidation:Electronicrecordsanddigitalsignature-21CFRPart11andGAMP

Unit-6: **10Hrs**

General PrinciplesofIntellectual Property:ConceptsofIntellectual Property (IP),IntellectualPropertyProtection(IPP),IntellectualPropertyRights(IPR);Economicimportance,mechanismforprotectionofIntellectual Property - patents,Copyright,Trademark;FactorsaffectingchoiceofIPprotection;Penaltiesforviolation;RoleofIPinpharmaceuticalindustry;Globalramificationandfinancialimplications.Filingapatentapplications;patentapplicationformsandguidelines.Typespatentapplications-provisionalandnon provisional,PCTand convention patentapplications;Internationalpatentingrequirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regardingmaintainingofaPatentfile;Patentinfringementmeaningandscope.Significanceoftransfertechnology(TOT),IPandethics-positiveandnegativeaspectsofIPP;Societalresponsibility,avoidingunethicalpractices.

REFERENCEBOOKS:

1. B.T.Loftus&R.A.Nash,"PharmaceuticalProcessValidation",DrugsandPharmSci.Series, Vol.129,3rdEd.,MarcelDekkerInc.,N.Y.
2. TheTheory&PracticeofIndustrialPharmacy,3rdedition,LeonLachman,HerbertA.Lieberman,Joseph.L.Karig,VarghesePublishingHouse,Bombay.
3. ValidationMasterplanbyTerveeksorDeeks,DavisHarwoodInternationalpublishing.
4. ValidationofAsepticPharmaceuticalProcesses,2ndEdition,byCarleton&Agalloco,
5. (MarcelDekker).
6. MichaelLevin,PharmaceuticalProcessScale-Up",DrugsandPharm.Sci.Series,Vol. 157,2ndEd.,MarcelDekkerInc.,N.Y.
7. Validation Standard Operating Procedures: A Step by Step Guide for AchievingComplianceinthePharmaceutical,MedicalDevice,andBiotechIndustries,SyedImtiaz Haider
8. PharmaceuticalEquipment Validation:TheUltimateQualificationHandbook,PhillipA.Cloud,InterpharmPress

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9. ValidationofPharmaceuticalProcesses:SterileProducts,FrederickJ.Carlton(Ed.)and JamesAgalloco(Ed.),MarcelDekker
10. AnalyticalMethodvalidationandInstrument PerformanceVerificationbyChurgChan,HeimanLam,Y.C.Lee,Yue.Zhang,WileyInterscience.
11. HuberL.ValidationandQualificationinAnalyticalLaboratories.InformaHealthcare
12. WingateG.ValidatingCorporateComputerSystems:GoodITPracticefor PharmaceuticalManufacturers.InterpharmPress
13. LeBlancDA.ValidatedCleaningTechnologiesforPharmaceuticalManufacturing. InterpharmPress

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AUDITSANDREGULATORYCOMPLIANCE(MPA203T)

THEORY **60Hours**

Scope

Thiscoursedealswiththeunderstandingandprocessforauditing inpharmaceuticalindustries. Thissubject covers the methodology involved in the auditing process of different in pharmaceuticalindustries.

ObjectivesUponcompletionofthiscoursethestudentshouldbeab letoTo

- understand the importance of
- auditingTounderstandthemethodologyofauditing
- Tocarryoutthe
- auditprocessTopreparetheauditingreportToprepa
- rethechecklistforauditing

Unit-1: **12Hrs**

Introduction:Objectives,Managementofaudit,Responsibilities,Planningprocess,information gathering,administration,Classifications ofdeficiencies.

Unit-2: **12Hrs**

Roleofqualitysystemsandauditsinpharmaceuticalmanufacturing environment:cGMPRegulations, Quality assurance functions, Quality systems approach, Managementresponsibilities,Resource,Manufacturingoperations,Evaluationactivities,Transitio ningtoqualitysystemapproach,Auditchecklistfordrugindustries.

Unit-3: **12Hrs**

Auditingofvendorsandproductiondepartment:BulkPharmaceuticalChemicalsandpackaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting,coating,capsules,sterile productionandpackaging.

Unit-4: **12Hrs**

AuditingofMicrobiologicallaboratory:Auditingthemanufacturingprocess,Productandprocessinf ormation,Generalareasofinterest inthebuildingrawmaterials, Water,Packagingmaterials.

Unit-5: **12Hrs**

AuditingofQualityAssuranceandengineeringdepartment:QualityAssuranceMaintenance, Criticalsystems:HVAC,Water,WaterforInjectionsystems,ETP.

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REFERENCEBOOKS:

1. ComplianceauditingforPharmaceuticalManufacturers.KarenGinsburyandGilBismuth,Interpharm/CRC,BocaRaton,LondonNewYork,WashingtonD.C.
2. PharmaceuticalManufacturingHandbook,RegulationsandQualitybyShayneCoxGad. Wiley-Interscience,AJohnWileyandsons,Inc.,Publications.
3. HandbookofmicrobiologicalQualitycontrol.RosamundM.Baird,Norman A.Hodges,StephenP.Denyar.CRCPress.2000.
4. Laboratoryauditingforqualityandregulatorycompliance.DonaldC.Singer,Raluca-loanaStefan,JacobusF.VanStaden.TaylorandFrancis(2005).

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PHARMACEUTICALMANUFACTURINGTECHNOLOGY(MQA204T)

THEORY **60Hours**

Scope

Thiscourseisdesignedtoimpartknowledgeandskillsnecessarytotrainthestudentswiththeindustrialactivitiesduring PharmaceuticalManufacturing.

Objectives

Atcompletionofthiscourseitisexpectedthatstudentswillbeabletounderstand,

- Thecommonpracticeinthepharmaceuticalindustrydevelopments,plantlayoutand productionplanning
- Willbefamiliarwiththeprinciplesandpracticesofasepticprocesstechnology,nonsterile manufacturingtechnologyandpackagingtechnology.
- HaveabetterunderstandingofprinciplesandimplementationofQualitybydesign(QbD)andprocessanalyticaltechnology(PAT)inpharmaceuticalmanufacturing

Unit-1: **12Hrs**

Pharmaceutical industry developments: Legal requirements and Licenses for API andformulationindustry,Plantlocation-Factorsinfluencing.Plantlayout:Factorsinfluencing,Specialprovisions,Storagespacerequirements,sterileand asepticarealayout.

Productionplanning:Generalprinciples,productionsystems,calculationofstandardcost,processplanning,routing,loading,scheduling,dispatchingofrecords,productioncontrol.

Unit-2: **12Hrs**

Asepticprocesstechnology:Manufacturing, manufacturingflowcharts,inprocess-qualitycontroltests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder,Solution (Small Volume & large Volume). Advancedsterileproductmanufacturing technology:Area planning & environmental control, wall and floor treatment, fixtures andmachineries,changerooms,personnelflow,utilities&utilitiesequipmentlocation,engineeringandmaintenance. Process Automation in Pharmaceutical Industry: With specific reference tomanufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals(SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP),SterilizationinPlace(SIP),PrefilledSyringe,PowderedJet, Needle Free Injections, and Form FillSealTechnology(FFS).

Unit-3: **12Hrs**

Lyophilization technology: Principles, process, equipmentNonsterilemanufacturingprocesstechnology:Manufacturing,manufacturingflowcharts,inprocess-qualitycontroltestsfor followingNon-Sterilesoliddosageforms:Tablets(compressed&coated),Capsules(Hard&Soft).

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Advancenon-sterilesolidproductmanufacturing

technology: Process Automation in Pharmaceutical Industry with specific reference tomanufacturingoftabletsandcoatedproducts,ImprovedTabletProduction:Tabletproductionprocess,granulationandpelletizationequipments,continuousandbatch mixing,rapidmixinggranulators, rota granulators, spheronizers and marumerisers, and other specialized granulation anddryingequipments.Problemsencountered.Coatingtechnology:Process,equipments,particlecoating,fluidizedbedcoating,applicationtechniques.Problemsencountered.

Unit-4: **12Hrs**

Containers andclosuresforpharmaceuticals:Types,performance,assuringqualityof glass;typesofplasticsused,Drugplasticinteractions,biologicaltests,modificationofplasticsbydrugs;differenttypesofclosuresandclosureliners;film wrapper;blisterpacks;bubblepacks;shrinkpackaging; foil/plasticpouches, bottleseals,tapeseals,breakablesealsand sealedtubes;qualitycontrolofpackagingmaterialandfillingequipment,flexiblepackaging,productpackagecompatibility,transitworthinessofpackage,Stabilityaspectsofpackaging.Evaluationofstabilityofpackagingmaterial.

Unit-5: **12Hrs**

Qualitybydesign(QbD)andprocessanalyticaltechnology(PAT):Currentapproachanditslimitations.WhyQbDisrequired,Advantages,Elements ofQbD,Terminology:QTPP.CMA,CQA,CPP,RLD,Designspace,DesignofExperiments,Risk Assessmentandmitigation/minimization.QualitybyDesign,FormulationsbyDesign,QbDfor drugproducts,QbDforDrugSubstances,QbDforExcipients,AnalyticalQbD.FDAinitiativeon processanalyticaltechnology.PATasadriverforimprovingqualityandreducingcosts:quality by design(QbD), QA, QCand GAMP.PATguidance, standardsandregulatoryrequirements.

REFERENCEBOOKS:

1. LachmanL,LiebermanHA,KanigJL.Thetheoryandpracticeofindustrial pharmacy,3rded.,Varghese Publishers,Mumbai1991.
2. SinkoPJ.Martin'sphysicalpharmacyandpharmaceuticalsciences,5th ed.,B.I.P ublicationsPvt.Ltd,Noida,2006.

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QUALITYASSURANCE PRACTICAL–III PRACTICALS(MQA205P)

Pharmaceuticalvalidation

1 Organiccontaminantsresidueanalysisby HPLC
2 SystemsuitabilityparametersforGradientHPLC
3 EstimationofMetalliccontaminantsbyFlamephotometer
4 IdentificationofantibioticresiduebyTLC
5 EstimationofHydrogenSulphideinAir.
6 EstimationofChlorineinWorkEnvironment.
7 SamplingandanalysisofSO2usingColorimetricmethod
8 QualificationoffollowingPharmaequipment

a. Autoclave
b. HotairovenC.PowderMixer
(Dry)d.TabletCompressionM
achine

9 Validationofananalyticalmethodforadrugby UV&HPLC
10 Validationofaprocessingarea
11 Qualificationofatleasttwoanalyticalinstruments
12 Cleaningvalidationofoneequipment
13 QualificationofPharmaceuticalTestingEquipment(Dissolutiontestingapparatus, FriabilityApparatus,DisintegrationTester)

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QUALITYASSURANCE PRACTICAL–IV PRACTICALS(MQA206P)

PharmaceuticalManufacturingTechnology

1 ChecklistforBulkPharmaceuticalChemicalsvendors
2 Checklistfortabletingproduction.
3 Checklistforsterileproductionarea
4 ChecklistforWaterforinjection.
5 Demonstratingtheprocessoftabletcompressionusingatabletpunching machine.
6 Hands-ontrainingoncapsule filling machinestounderstandtheprocessoffillingpowders,pellets,orgranulesin tohardgelatincapsules
7 Formulationandmanufacturingofcreamsandointments.
8 Performingqualitycontroltestsonpharmaceuticalproducts, includingidentificationtests,assaydetermination,dissolutiontesting,and contentuniformitytests.
9 PracticalexercisesonGoodManufacturingPractices(GMP)
10 Preparationofsuppositoriesusingdifferentbasesandactiveingredients.
11 Practicalsessionsonregulatoryrequirementsandcomplianceinpharmaceutical manufacturing
12 Designofplantlayout:Sterileandnon-sterile
13 CasestudyonapplicationofQbDCasestudyonapplicationofPAT.

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PHARMACEUTICALREGULATORYAFFAIRS
GOODREGULATORYPRACTICES(MRA101T)

THEORY **60Hours**

Scope:

This course is designed to impart fundamental knowledge on various GoodRegulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals,Cosmetics,Food&Nutraceuticals,Medicaldevices,In-vitroDiagnosticMedicalDevices(IVDs)andbiologicalproductsandunderstandtheration alebehindtheserequirementsand willpropose waysandmeansofcomplying withthem.

Objectives

At completion of this course it is expected that students will be able to understand,ThekeyregulatoryandcomplianceelementswithrespecttogoodmanufacturingPractices,GoodLaboratoryPractices,GoodAutomatedLaboratoryPracticesandGood DocumentationPractices.

- Prepareandimplementthechecklistsand SOPsforvariousGoodRegulatory
- PracticesImplementGoodRegulatoryPracticesintheHealthcareandrelatedIndustriesPrepare
- forthereadinessandconductofauditsandinspections

Unit-1: **12Hrs**

CurrentGoodManufacturingPractices:Introduction,UScGMPPart210andPart211.EC PrinciplesofGMP(Directive91/356/EEC)Article6toArticle14andWHO cGMPguidelinesGAMP-5; Medical device and IVDs Global Harmonization TaskForce(GHTF)Guidancedocs.

Unit-2: **12Hrs**

Good LaboratoryPractices: Introduction, USFDAGLP Regulations(Subpart Ato Subpart K),ControllingtheGLPinspectionprocess, Documentation,Audit, goalsofLaboratoryQualityAudit,Audit tools,FutureofGLPregulations,relevant ISOandQualityCouncilofIndia(QCI)Standards

Unit-3: **12Hrs**

GoodAutomatedLaboratoryPractices:IntroductiontoGALP,PrinciplesofGALP,GALPRequirements,SOPsofGALP,TrainingDocumentation,21CFRPart 11,Generalcheck list of21CFRPart11,SoftwareEvaluationchecklist,relevantISOandQCIStandards.

Unit-4: **12Hrs**

Good Distribution Practices: Introduction to GDP, Legal GDP requirements put worldwide,Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers,Returns,Self-Inspection,Provisionofinformation,Stabilitytestingprinciples,WHOGDP,USPGDP(Supplychainintegrity),relevantCDSCO guidance andISO standards.

Unit-5: **12Hrs**

Quality management systems: Concept of Quality, Total Quality Management, Quality bydesign, SixSigma concept,Out ofSpecifications(OOS), Change control. Validation: TypesofValidation, Types of Qualification, Validation master plan (VMP), Analytical MethodValidation.Validationofutilities,[Compressedair,steam,watersystems,Heat Ventilationand Airconditioning (HVAC)]and Cleaning Validation. The International Conference onHarmonization(ICH)process,ICHguidelinesto establishquality,safetyand efficacyofdrugsubstances and products, ISO13485,SchMIII andother relevant CDSCO regulatoryguidancedocuments

REFERENCEBOOKS

1. GoodLaboratoryPracticeRegulations,bySandyWeinberg,FourthEditionDrugsandthe PharmaceuticalSciences,Vol.168

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DOCUMENTATION AND REGULATORYWRITING(MRA102T)

THEORY **60Hours**

Scope

Thiscourseisdesignedto impart fundamentalknowledgeondocumentationandgeneral principlesinvolvedinregulatorywritingandsubmissiontoagencies.

Objectives

Uponcompletionofthecoursethestudentshallbeableto,Knowthevariousdocumentsp

ertainingtodrugsinpharmaceuticalindustry Understandthebasics

ofregulatorycompilation

Createandassembletheregulationsubmissionaspertherequirementsofagencies Followupthe

submissionsandpostapprovaldocumentrequirements

Unit-1: **12Hrs**

Documentation in pharmaceutical industry: ExploratoryProductDevelopmentBrief(EPDB) for Drug substance and Drug product, Product Development Plan (PDP), ProductDevelopment Report(PDR),MasterFormulaRecord,BatchManufacturingRecordanditscalculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications,Distributionrecords,Certificate ofAnalysis(CoA), Site Master File and Drug Master Files(DMF)

Unit-2: **12Hrs**

Dossierpreparationandsubmission:Introduction andoverviewofdossiers,contentsando rganization of dossier, binders and sections, compilation and review of dossier. Papersubmissions, overview and modules of CTD, electronic CTD submissions; Electronicsubmission:Planningelectronicsubmission,requirementsforsubmission,regulatorybin dingsand requirements, Tooland Technologies, electronicdossier submissionprocessand validatingthe submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions(NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation ofsubmission.SubmissioninSugamsystemofCDSCO

Unit-3: **12Hrs**

Audits:Introduction,Definition,Summary,Typesofaudits,GMPcomplianceaudit,Auditpolicy,InternalandExte

rnalAudits,SecondPartyAudits,Externalthirdpartyaudits,Auditing strategies,Preparationandconductingaudit,Auditingstrategies,auditanalysis,auditreport, auditfollowup.Auditing/inspectionofmanufacturingfacilitiesbyregulatoryagencies.

Timelinesforaudits/inspection.GHTFstudygroup4guidancedocument.ISO13485.

Unit-4: **12Hrs**

Inspections: Pre-approval inspections, Inspection ofpharmaceuticalmanufacturers, Inspection of drug distribution channels, Quality systems requirements for national goodmanufacturingpracticeinspectorates,inspectionreport,modelcertificateofgoodmanufacturing practices,Rootcauseanalysis,Corrective andPreventiveaction(CAPA).

Unit-5: **12Hrs**

Product life cycle management: Prior Approval Supplement (PAS), Post Approval Changes[SUPAC],ChangesBeingEffectedin30Days(CBE-30),AnnualReport,PostmarketingReportingRequirements,PostapprovalLabeling Changes,Lifecycle Management,FDAInspectionandEnforcement,EstablishmentInspectionReport(EIR),WarningLetters,Recalls,Seizure andInjunctions.ISO RiskManagementStandard.

REFERENCEBOOKS

1. ComplianceauditingforPharmaceuticalManufacturers.KarenGinsburyandGilBismuth,Interpharm/CRC,BocaRaton,LondonNewYork,WashingtonD.C.
2. PharmaceuticalManufacturingHandbook,RegulationsandQualitybyShayneCox Gad.Wiley-Interscience,AJohnWileyand sons,Inc.,Publications.
3. HandbookofmicrobiologicalQualitycontrol.RosamundM.Baird,NormanA. Hodges,StephenP.Denyar.CRCPress.2000.
4. Laboratoryauditing forqualityandregulatorycompliance.DonaldC.Singer,Raluca-loanaStefan,JacobusF.VanStaden.TaylorandFrancis(2005).
5. ImplementingJuran'sRoadMapforQualityLeadership:BenchmarksandResults,By AlEndres,Wiley,2000
6. Understanding,ManagingandImplementingQuality:Frameworks,Techniquesand Cases,ByJijuAntony;DavidPreece,Routledge,2002

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CLINICAL RESEARCHREGULATIONS(MRA103T)

THEORY **60Hours**

Scope

This course is designed to impart the fundamental knowledge on the clinicaldevelopment process of drugs, pharmaceuticals and Medical Devices, phases andconduct of clinical trials and research, regulations and guidance governing theconductofclinicalresearch inIndia,USAand EU.

Itpreparesthestudentstolearnindetailonvariouslaws,legislationsandguidancerelatedtosafety,efficacy,ethicalconductandregulatoryapprovalofclinicalresearch.

Objectives

Uponcompletionofthecourse,thestudent shallbeableto(know,doand
Γappreciate)History, origin and ethics of clinical and biomedical research and
Γevaluation Clinicaldrug,medicaldevicedevelopmentprocessanddifferenttypesa
ndphases
ofclinicaltrials
I Regulatoryrequirementsandguidanceforconductofclinicaltrialsandresearch

Unit-

Γ**1:**ClinicalDrugDevelopmentProcessDifferent
Γtypes of Clinical
ΓStudiesPhasesofclinicaltrials,ClinicalTrialproto
colPhase 0studies
Γ Phase I and subtype studies (single ascending, multiple ascending, doseescalation,methods,foodeffectstudies,drug–druginteraction,PKendpoints
Γ PhaseIIstudies(proofofconceptorprinciplestudiestoestablishefficacy)PhaseIIIstudie
Γ s(Multiethnicity,globalclinicaltrial,registrationstudies)
Γ PhaseIVstudies(PostMarketingStudies;PSUR)ClinicalInvestigati
onandEvaluationofMedicalDevices&IVDs
Different Types ofStudies: Key Concepts ofMedicalDevice Clinical EvaluationKeyconcepts ofClinicalInvestigation **12hrs**

Unit-2:EthicsinClinicalResearch:

•HistoricalPerspectives:NurembergCode,Thalidomidestudy ,NazisTrials,TuskegeeSyphilisStudy,TheBelmontReport,ThedeclarationofHelsinki
•OriginofInternationalConferenceonHarmonization-GoodClinicalPractice(ICH-GCP)guidelines.
•Theethicsofrandomizedclinicaltrials•Theroleofplaceboinclinicaltrials
•Ethicsofclinicalresearchinspecialpopulation

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- Institutional Review Board/Independent EthicsCommittee/EthicsCommittee – composition, roles,responsibilities,reviewand approvalprocessandongoingmonitoringofsafetydata
- Datasafetymonitoringboards.
- Responsibilitiesofsponsor, CRO,and investigatorinethicalconductofclinicalresearch
- Ethicalprinciplesgoverninginformedconsentprocess
- PatientInformationSheetandInformedConsentForm
- The informedconsentprocessanddocumentation

12hrsUnit-3. RegulationsgoverningClinicalTrials

India:ClinicalResearchregulationsinIndia– ScheduleY&MedicalDeviceGuidanceUSA:Regulationstoconductdrugstudiesin USA(FDA)

- NDA505(b)(1)oftheFD&CAct(Applicationforapprovalofanewdrug)NDA505(b)(2)oftheFD&C
- Act(Applicationforapprovalofanewdrugthatrelies,atleastinpart, ondatanotdevelopedbytheapplicant)
- ANDA505(j)oftheFD&CAct (Applicationforapprovalofagenericdrugproduct)
- FDAGuidanceforIndustry-Acceptance ofForeignClinical Studies
- FDAClinicalTrialsGuidanceDocument:GoodClinicalPracticeEU:ClinicalResearchregulatio nsinEuropeanUnion(EMA) **12hrs**

Unit-4 .Clinical ResearchRelated

- GuidelinesGoodClinicalPracticeGuidelines(ICH
- GCPE6)Indian
- GCPGuidelinesICMREthicalGuidelinesforBiome
- dicalResearchCDSCO guidelines

GHTFstudygroup5guidancedocuments

Regulatory Guidance onEfficacy and Safety ICH

- Guidance'sE4– DoseResponseInformationtosupportDrugRegistrationE7
- – Studies in support of General Population: GeriatricsE8–
- GeneralConsiderationsofClinicalTrialsE10–
- ChoiceofControlGroupsandRelated IssuesinClinicalTrials,
- E11–
- ClinicalInvestigationofMedicinalProductsinthePediatricPopulationGeneralbiostaticsprincip leappliedinclinicalresearch 12hrs

Unit-

- **5.**USA&EUGuidanceUSA:FDAGuidanceCFR21Part50:Protec

tionofHumanSubjects

⌐CFR21Part54:FinancialDisclosurebyClinicalInvestigatorsCFR

⌐21Part312:INDApplication

CFR21Part 314:ApplicationforFDAApprovaltoMarketaNewDrugCFR21Part320: Bioavailabilityandbioequivalence requirementsCFR21Part812:InvestigationalDeviceExemptions

⌐CFR21Part822:Post-

⌐marketsurveillanceFDASafetyReportingRequirementsforINDsandBA/BEStudies

⌐FDAMedWatchGuidanceforIndustry:GoodPharmacovigilancePracticesandPharmacoepidemiologicAssessmentEuropeanUnion:EMAGuidance

⌐EUDirectives2001

⌐EudraLex(EMEA)Volume3 –Scientificguidelinesformedicinalproductsforhumanuse

⌐EUAnnualSafetyReport(ASR)

⌐Volume9A–

⌐PharmacovigilanceforMedicinalProductsforHumanUseEUMDD withrespecttoclinicalresearch

⌐ISO14155 **12hrs**

REFERENCEBOOKS

1. ClinicalTrialsandHumanResearch:APracticalGuidetoRegulatoryComplianceByFay A.RozovskyandRodneyK.Adams
2. HIPAAandHumanSubjectsResearch:AQuestionandAnswerReferenceGuideByMark Barnes,JD,LLMandJenniferKulynych,JD,PhD
3. PrinciplesandPracticesofClinicalResearch, SecondEditionEditedbyJohnI. Gallin andFrederickP.Ognibene
4. ReviewingClinicalTrials:AGuidefortheEthicsCommittee;JohanPEKarlbergand MarjorieASpeers;Karlberg,JohanPetterEinar,HongKong.
5. InternationalPharmaceuticalProduct Registration: AspectsofQuality,SafetyandEfficacy;AnthonyC.Cartwright;Taylor&FrancisInc.,USA.
6. NewDrugApprovalProcess:TheGlobalChallenge;Guarino,RichardA;Marcel DekkerInc.,NY.
7. FDAregulatoryaffairs:aguide forprescriptiondrugs,medicaldevices,and biologics;DouglasJ.Pisano,DavidMantus;CRC Press,USA
8. CountrySpecificGuidelinesfromofficialwebsites.Drugs&CosmeticsAct&RulesandAmendments

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REGULATIONSANDLEGISLATIONFORDRUGS&COSMETICS,MEDICALDEVICES,BIOLOGICALS&HERBALS,ANDFOOD&NUTRACEUTICALSININDIA ANDINTELLECTUALPROPERTYRIGHTS
(MRA104T)

THEORY **60Hours**

Scope
Thiscourseisdesignedtoimpartfundamentalknowledgeonregulationsandlegislationin India w.r.t.Drugs&Cosmetics,MedicalDevices,Biologicals&Herbals,andFood&Nutraceuticals.Itprepares the students for basic regulatory requirements in India of Drugs & Cosmetics,MedicalDevices,Biologicals&Herbals,andFood&Nutraceuticals.formanufacture,import&registration, export, sale, marketing authorization, clinical trials and intellectualpropertyrights.**Objectives**
Uponthecompletionofthecoursethestudentshallbeableto:

- Knowdifferent Actsandguidelinesthat regulateDrugs&Cosmetics,MedicalDevices,Biologicals&Herbals,andFood&Nutraceuticalsindustry inIndia.
- Understand the approvalprocessandregulatoryrequirementsforDrugs&Cosmetics,MedicalDevices,Biologicals&Herbals,andFood&Nutraceuticals

Unit-1:Biologicals&Herbals,andFood&NutraceuticalsActsandRules(withlatestamendments):

1. DrugsandCosmeticsAct1940andRules1945:DPCOandNPPA
2. Otherrelevantprovisions(rulesschedulesandguidelinesforapprovalofDrugs&Cosmetics,MedicalDevices,Biologicals&Herbals,andFood&NutraceuticalsinIndia

Other relevant Acts: Narcotics Drugs and Psychotropic Substances Act; Medicinaland ToiletPreparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies(ObjectionableAdvertisements) Act, 1955;PreventionofCrueltytoAnimals Act.
10Hrs

Unit-2: Regulatory requirements and approval proceduresforDrugs & Cosmetics MedicalDevices, Biologicals & Herbals, and Food & Nutraceuticals CDSCO (CentralDrug StandardControlOrganization)andStateLicensingAuthority:Organization,Responsibilities
10hrs

- Rules,regulations,guidelinesandstandardsforregulatoryfilingofDrugs&Cosmetics,MedicalDevices,Biologicals&Herbals,andFood&Nutraceuticals
- FormatandcontentsofRegulatorydossierfilingClinicaltrial/investigations

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Unit-3: IndianPharmacopoeialStandards,BISstandardsandISOandotherrelevantstandards 10Hrs

Unit-4: Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs,Regulatory Requirements for Bioequivalence study Stability requirements:ICH and WHOGuidelines for Drug testing in animals/Preclinical StudiesAnimal testing: Rationale forconductingstudies,CPCSEAGuidelinesEthicalguidelinesforhumanparticipantsICMR-DBTGuidelinesforStemCellResearch 10Hrs

Unit-5: Intellectual Property Rights: Patent, Trademark, Copyright, Industrial Designs andGeographicalIndications, IndianPatentScenario. IPRvsRegulatoryAffairs. 10Hrs

REFERENCEBOOKS

1. ManualofPatentPractice&Procedure,3rdEdition,byThePatentOfficeofIndia
2. PatentFailureHowJudges,Bureaucrats,andLawyersputinnovatorsatriskbyJames BessenandMichaelJ.Meurer
3. PrinciplesandPracticeofClinicalTrialMedicinebyRichardChinandBruceY.Lee
4. EthicalGuidelinesforBiomedicalResearchonHumanParticipantsbyIndianCouncilof MedicalResearchNewdelhi2006.

CPCSEAGuidelines for LaboratoryAnimalFacilitybyCommitteeforthepurposeofcontrol andsupervisiononexperiments onanimals(CPCSEA)

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REGULATORYAFFAIRS PRACTICAL-I(MRA105P)

ListofExperiments:

1. Casestudies(4Nos.)ofeachofGoodPharmaceuticalPractices.
2. Documentationforinprocessand finishedproductsQualitycontroltestsforSolid,liquid,SemisolidandSterile preparations.
3. PreparationofSOPs,Analyticalreports(Stabilityandvalidation)
4. Protocolpreparationfordocumentationofvarioustypesofrecords(BMR,MFR, DR)Labelingcomparisonbetweenbrand&generics.
5. PreparationofregulatorydossierasperIndianCTDformatandsubmissioninSUGAM
6. CasestudiesonresponsewithscientificrationaletoUSFDAWarningLetter
7. PreparationofsubmissionchecklistofIMPDforEUsubmission.
8. ComparisonstudyofmarketingauthorizationproceduresinEU.

REGULATORYAFFAIRSPRACTICAL–II(MRA106P)

ListofExperiments:

1. CasestudiesonChangeManagement/Changecontrol.DeviationsandCorrective& Preventive Actions (CAPA)
2. Importofdrugsforresearchanddevelopmentalactivities
3. GMPAuditRequirementsasperCDSCO
4. PreparationofchecklistforregistrationofINDasperICHCTDformat.
5. PreparationofchecklistforregistrationofNDAasperICHCTDformat.
6. PreparationofchecklistforregistrationofANDAasperICHCTDformat.
7. ComparativestudyofDMFsysteminUS,EUandJapan
8. PreparationofregulatorysubmissionusingeCTDsoftware
9. Documentationofrawmaterialsanalysisasperofficialmonographs
10. Preparationofauditchecklistforvariousagencies
11. PreparationofsubmissiontoFDAusing eCTDsoftware
12. PreparationofsubmissiontoEMAusingeCTDsoftware
13. PreparationofsubmissiontoMHRAusingeCTDsoftware

SEMESTERII

REGULATORYASPECTSOFDRUGS&COSMETICS(MRA201T)

THEORY **60Hours**

Scope

Thiscourseisdesignedtoimpartthefundamentalknowledgeonthedrugdevelopmentprocess,regulatoryrequirementsforapprovalofnewdrugs,drugproductsandcosmeticsinregulatedand semi-regulatedcountriesItpreparesthestudentstolearnindetailontheregulatoryrequirements,documentation requirements, and registration procedures for marketing the drug products andcosmeticsinregulatedandsemi-regulatedcountries.

Objectives

Uponcompletionofthe course,thestudentshallbe

- ableto know processofdrugdiscoveryanddevelopmentandgenericproductdevelopmentregulatorya
- pprovalprocessandregistrationproceduresforAPIanddrugproductsinUS,EUCosmeticsregulations
- inregulatedandsemi-
- regulatedcountriesAcomparativestudyofIndiawithotherglobalregulatedmarkets

Unit-1. USA & CANADA: Organization structure and functions of FDA. Federal register andCode of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drugand Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug MasterFiles(DMF)systeminUS,RegulatoryApproval

Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated NewDrugApplication(ANDA),SupplementalNewDrugApplication(SNDA);Regulatoryrequirements for Orphan drugs and Combination Products, Changes to an approved NDA /ANDA.Regulatoryconsiderationsfor manufacturing,packagingand labelingofpharmaceuticals inUSA. Legislation and regulations for import, manufacture, distribution and sale of cosmeticsinUSAand Canada. **12Hrs**

Unit-2: European Union & Australia: Organization and structure of EMA & EDQM, Generalguidelines, Active Substance Master Files (ASMF) system in EU, Content and approvalprocessofIMPD,MarketingAuthorizationproceduresinEU(Centralizedprocedure Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatoryconsiderations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralexdirectivesforhumanmedicines,Variations&extensions,ComplianceofEuropeanPharmacopoeia(CEP)/Certificateof Suitability (CoS), Marketing Authorization (MA) transfers,Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distributionandsaleofcosmeticsinEuropeanUnion&Australia. **12HRS**

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Unit-3:Japan:OrganizationofthePMDA,PharmaceuticalLawsandregulations,typesofregistrationapplications,DMF systeminJapan,drugregulatory approval process,Regulatoryconsiderationsformanufacturing,packagingandlabelingofpharmaceuticalsinJapan,PostmarketingsurveillanceinJapan.Legislationandregulationsforimport,manufacture,distributionandsaleofcosmeticsinJapan. **12 Hrs**

Unit-4.EmergingMarket:Introduction,Countriescovered,Studyoftheworldmap,studyof variouscommitteesacrossthe globe(ASEAN,APEC,EAC,GCC,PANDRH,SADC) WHO:WHO,GMP,RegulatoryRequirementsforregistrationofdrugsandpostapprovalrequirementsinWHOthroughprequalificationprogramme,CertificateofPharmaceuticalProduct (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco,Nigeria,KenyaandBotswana) **12hrs**

Unit-5.Brazil,ASEAN,CISandGCCCountries:ASIANCountries:IntroductiontoACTD,Regulatory Requirements for registration of drugs and postapproval requirements inChinaandSouthKorea&AssociationofSoutheastAsianNations(ASEAN)Regioni.e.Vietnam,Malaysia,Philippines,SingaporeandThailand.
CIS(CommonwealthIndependentStates):Regulatorypre-requisitesrelatedtoMarketingauthorizationrequirementsfordrugsandpostapprovalrequirementsinCIScountriesi.e.Russia,Kazakhstan and Ukraine GCC (Gulf Cooperation Council)forArab states:Regulatory pre-requisitesrelatedtoMarketingauthorizationrequirementsfordrugsandpostapprovalrequirements in Saudi Arabia and UAE Legislation and regulations for import, manufacture,distributionandsaleofcosmeticsinBrazil,ASEAN,CISandGCCCountries. **12hrs**

REFERENCEBOOKS

1. GenericDrugProductDevelopment,SolidOralDosage forms,LeonShargelandIsaderKaufer,MarcelDekkerseries,Vol.143
2. ThePharmaceuticalRegulatoryProcess,EditedbyIraR.BerryMarcelDekkerSeries,Vol.144
3. ThePharmaceuticalRegulatoryProcess,SecondEditionEditedbyIraR.BerryandRobertP.Martin,Drugsand thePharmaceuticalSciences,Vol.185InformaHealthcarePublishers
4. Guidebookfordrugregulatorysubmissions/SandyWeinberg.ByJohnWiley&Sons.Inc

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REGULATORYASPECTSOFHERBALANDBIOLOGICALS(MRA202T)

THEORY **60Hours**

Scope

ThiscourseisdesignedtoimpartfundamentalknowledgeonRegulatoryRequirements,LicensingandRegistration, Regulation on Labelling of Biologics in India, USA and EuropeItpreparesthestudentstolearnindetailonRegulatoryRequirementsforbiologics, Vaccinesand BloodProducts

Objectives

Uponthecompletionofthecoursethestudentshallbeableto:

•KnowtheregulatoryRequirementsforBiologicsandVaccines

•Understandtheregulationfornewlydeveloped biologicsandbiosimilars

•Knowthepre-clinicalandclinicaldevelopmentconsiderationsofbiologics

•UnderstandtheRegulatoryRequirementsofBloodand/orItsCo mponentsIncludingBloodProductsandlabelrequirements

Unit1: India : Introduction, Applicable Regulations and Guidelines , Principles for Developmentof Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for ClinicalTrial Application, Data Requirements for Market AuthorizationApplication,Post-Market DataforSimilarBiologics, Pharmacovigilance. GMPandGDP. **12HRS**

Unit-2:USA:IntroductiontoBiologics;biologics,biologicalandbiosimilars,differentbiologicalproducts, difference between generic drug and biosimilars, laws, regulations and guidance onbiologics/biosimilars,developmentandapprovalofbiologicsandbiosimilars(IND,PMA,BLA,ND A, 510(k), pre-clinical and clinical development considerations, advertising, labelling andpackingofbiologics. **12hrs**

Unit-3.EuropeanUnion:IntroductiontoBiologics;directives,scientificguidelinesandguidancerelatedtobio logicsinEU,comparability/biosimilarityassessment,Plasmamasterfile,TSE/BSE evaluation, development and regulatory approval of biologics(Investigationalmedicinalproductsandbiosimilars),pre-clinicalandclinicaldevelopmentconsiderations;stability, safety,advertising,labellingandpackingofbiologicsinEU**12Hrs**

Unit-4. Vaccine regulations in India, US and European Union: Clinical evaluation, Marketingauthorisation,Registrationorlicensing,Qualityassessment,Pharmacovigilance,Additiona lrequirementsBloodandBloodProductsRegulationsinIndia,USandEuropeanUnion:RegulatoryReq uirementsofBloodand/orItsComponentsIncludingBloodProducts,

LabelRequirements,ISBT (International Society of Blood Transfusion) and IHN (InternationalHaemovigilenceNetwork) **12hrs**

5. HerabalProducats:Quality,safetyandlegislationforherbalproductsinIndia,USAand EuropeanUnion **12hrs**

REFERENCEBOOKS

1. FDARegulatoryAffairs:AGuideforPrescriptionDrugs,MedicalDevices,andBiologics,D ouglasJ.Pisano,DavidS.Mantus;Informa ,2008
2. DevelopmentofVaccines:FromDiscoverytoClinicalTesting;ManmohanSingh,IndreshK.Srivast ava;Wiley,2011
3. BiologicalDrugProducts:DevelopmentandStrategies;WeiWang,ManmohanSingh;wiley ,2013

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REGULATORYASPECTSOFMEDICALDEVICES(MRA203T)

THEORY **60Hours**

Scope

Thiscourseisdesignedtoimpartthefundamentalknowledgeonthemedicaldevicesandinvitrodiagnostics,basisofclassificationandproductlifecycleofmedicaldevices,regulatoryrequirements for approval of medical devices in regulated countries like US, EU and AsiancountriesalongwithWHOregulations.Itpreparesthestudentstolearnindetailontheharmonizationinitiatives,qualityandethicalconsiderations,regulatoryanddocumentationrequirementsformarketingmedicaldevicesandIVDsinregulatedcountries.

Objectives

Uponcompletionofthecourse,thestudentshallbeabletoknow

•basicsofmedicaldevicesandIVDs,processofdevelopment,ethicalandqualityconsiderations

•harmonizationinitiativesforapprovalandmarketingofmedicaldevicesandIVDs

•regulatoryapprovalprocessformedicaldevicesandIVDsinIndia,US,Canada,EU,JapanandASEAN

•clinicalevaluationandinvestigationofmedicaldevicesandIVDs

Unit-1 Medical Devices: Introduction, Definition, Risk based classification and EssentialPrinciplesofMedicalDevicesandIVDs.Differentiating medicaldevicesIVDsandCombinationProductsfromthatofpharmaceuticals,HistoryofMedicalDeviceRegulation,ProductLifecycleofMedicalDevices andClassificationofMedicalDevices. IMDRF/GHTF:Introduction,OrganizationalStructure,PurposeandFunctions,RegulatoryGuidelines, Working Groups, Summary Technical Document (STED), Global Medical DeviceNomenclature(GMDN). **12Hrs**

Unit-2:Ethics:ClinicalInvestigationofMedicalDevices,ClinicalInvestigationPlanforMedical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO14155:2011) Quality: QualitySystemRegulations of MedicalDevices: ISO 13485, QualityRiskManagement of Medical Devices: ISO 14971, Validation and Verification of Medical device,AdverseEventReporting ofMedicaldevice **12hrs**

Unit-3:USA:Introduction,Classification,Regulatory approval processforMedicalDevices(510k)PremarketNotification,Pre-MarketApproval (PMA),Investigational DeviceExemption(IDE)andInvitroDiagnostics,QualitySystemRequirements21CFRPart820,Labelingrequirements21CFRPart801,PostmarketingsurveillanceofMDandUniqueDeviceIdentification(UDI).BasicsofInvitrodiagnostics,classificationandapprovalprocess.**12Hrs**

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Unit-
4:EuropeanUnion:Introduction,Classification,RegulatoryapprovalprocessforMedicalDevices(MedicalDeviceDirective, ActiveImplantableMedicalDeviceDirective)andInvitroDiagnostics (In Vitro Diagnostics Directive), CE certification process. Basics of In vitrodiagnostics,classificationandapprovalprocess **12hrs**

Unit-5:ASEAN,China &Japan:MedicalDevicesandIVDs,Regulatoryregistration procedures,QualitySystemrequirementsandclinicalevaluationandinvestigation.

IMDRFstudygroupsand guidancedocuments.

12hrs

REFERENCEBOOKS:

1. FDAregulatoryaffairs:aguideforprescriptiondrugs,medicaldevices,andbiologics byDouglasJ.Pisano,DavidMantus.
2. MedicalDeviceDevelopment:ARegulatoryOverviewbyJonathanS.Kahan
3. MedicalProductRegulatoryAffairs:Pharmaceuticals,Diagnostics,MedicalDevicesby JohnJ.TobinandGaryWalsh
4. ComplianceHandbookforPharmaceuticals,MedicalDevicesandBiologicsbyCarmen MedinaCountrySpecificGuidelinesfromofficialwebsites

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REGULATORYASPECTSOFFOOD&NUTRACEUTICALS(MRA204T)

THEORY **60Hours**

Scope

This course is designed to impart the fundamental knowledge on RegulatoryRequirements,RegistrationandLabelingRegulationsofNutraceuticalsinIndia,USAandEurope.Itpreparesthestudentstolearnindetailon RegulatoryAspectsfornutraceuticalsanddfoodsupplements.

Objectives

Uponcompletionofthecourse,thestudent

- shallbeabletoKnowtheregulatoryRequirementsfornutraceuticals
- Understandtheregulationforregistrationand labelingofnutraceuticalsand foodsupplementsinIndia,USAandEurope.

Unit-1: Nutraceuticals: Introduction, History of Food and Nutraceutical Regulations,Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods,Scopeand OpportunitiesinNutraceuticalMarket. **12hrs**

Unit-2:GlobalAspects:WHOguidelinesonnutrition. NSFInternational:ItsRoleintheDietarySupplementsand NutraceuticalsIndustries, NSFCertification, NSFStandardsforFoodAndDietarySupplements.GoodManufacturingPracticesforNutraceuticals.**12hrs**

Unit-3:India:FoodSafetyandStandardsAct,FoodSafetyandStandardsAuthorityofIndia:Organization and Functions, Regulations for import, manufacture and sale ofnutraceuticalproductsinIndia,RecommendedDietaryAllowances(RDA)inIndia.

12hrs

Unit-4:USA:USFDAFoodSafetyModernizationAct,DietarySupplementHealthandEducation Act. U.S. regulations for manufacture and sale of nutraceuticals and dietarysupplements, Labelling Requirements and Label Claims for Dietary Supplements,RecommendedDietaryAllowances(RDA)intheU.S **12hrs**

Unit-5: European Union: European Food Safety Authority (EFSA): Organization andFunctions.EUDirectivesandregulationsformanufactureandsaleofnutraceuticalsanddietarysupplements. Nutritionlabelling.

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EuropeanRegulationonNovelFoodsandNovelFoodIngredients.
RecommendedDietaryAllowances(RDA)inEurope. **12Hrs**

REFEERENCEBOOKS:

1. RegulationofFunctionalFoodsandNutraceuticals:AGlobalPerspectivebyClare M.Hasler(WileyOnlineLibrary)

2. HandbookofNutraceuticalsbyYashwantPathak

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REGULATORYAFFAIRS PRACTICAL-III(MRA205P)

ListofExperiments:

1. PreparationofBiologicsLicenseApplications(BLA)
2. PreparationofdocumentsrequiredforVaccineProductApproval
3. ComparisonofclinicaltrialapplicationrequirementsofUS,EU andIndiaofBiologics
4. PreparationofChecklistforRegistrationofBloodandBloodProducts
5. Registrationrequirement comparisonstudyin5emergingmarkets(WHO) andpreparingchecklistformarketauthorization
6. Registrationrequirementcomparisonstudyinemergingmarkets(BRICS)andpreparing checklistformarketauthorization
7. Registrationrequirementcomparisonstudyinemergingmarkets(ChinaandSouth Korea)andpreparingchecklistformarketauthorization
8. Registrationrequirementcomparisonstudyinemergingmarkets(ASEAN)and preparingchecklistformarketauthorization
9. Registrationrequirementcomparisonstudyinemergingmarkets(GCC)andpreparing checklistformarketauthorization
10. Preparationofdocumentrequiredfortheapprovalofherbalproductsofdiversedosagef orms(3products)as perregulations requirements

REGULATORYAFFAIRSPRACTICAL-IV(MRA206P)

1. Checklistsfor510kandPMAforUSmarket
2. ChecklistforCEmarkingforvariousclassesofdevicesforEU
3. STEDApplicationforClassIIIDevices
4. AuditChecklistforMedicalDeviceFacility
5. ClinicalInvestigationPlanforMedicalDevices
6. Preparationandsubmissionofmedicaldevicesforapproval(3products)
7. GMPofmanufacturingofmedicaldevicesofdiversenature(3products)
8. preparationandsubmissionofnutraceuticalsdevicesforapproval(3products)

PHARMACYPRACTICECLINICALPHARMACYPRACTICE

(MPP101T)

THEORY **60Hours**

Scope: This course is designed to impart the basic knowledge and skills that arerequiredtopracticepharmacyincludingtheprovisionofpharmaceuticalcareservices tobothhealthcare professionals andpatientsinclinicalsettings.

Objectives

Uponcompletionofthiscourseitisexpectedthatstudentsshallbeableto:

- Understandtheelementsofpharmaceuticalcareandprovidecomprehensivepatient careservices
- Interpretthe
- laboratoryresultstoaidtheclinicaldiagnosisofvariousdisordersProvideintegrated,criticallyanalyzedmedicineandpoisoninformationtoenable healthcareprofessionalsintheefficientpatientmanagement

Unit-1: Introduction to Clinical Pharmacy:Definition, evolution and scope ofclinicalpharmacy,Internationalandnationalscenarioofclinicalpharmacypractice,Pharmaceutical care Clinical Pharmacy Services: Ward round participation, Drugtherapyreview (Drug therapy monitoring including medication order review, chartendorsement,clinicalreviewandpharmacistinterventions) **12hrs**

Unit-2: Clinical Pharmacy Services: Patient medication history interview, Basic conceptofmedicineandpoisoninformationservices,Basicconceptofpharmacovigilance,Hemovigilance,MateriovigilanceandAEFI,Patientmedicationcounselling,Drugutilisation evaluation, Documentation of clinical pharmacy services, Quality assurance ofclinicalpharmacyservices. **12hrs**

Unit-3:PatientDataAnalysis:PatientData&PracticeSkills:Patient'scasehistory-its structureandsignificancesindrugtherapymanagement,Commonmedicalabbreviationsandterminologiesusedinclinicalpractice,Communicationskills:verbal and non-verbal communications, its applications in patient care services LabDataInterpretation: Hematologicaltests,Renalfunctiontests,Liverfunctiontests

12hrs

Unit-4:LabDataInterpretation:Testsassociatedwithcardiacdisorders,Pulmonaryfunction tests,Thyroidfunction

tests,Fluidandelectrolytebalance,Microbiologicalculturesensitivitytests. **12Hrs**

Unit-5:Medicines&PoisonInformationServicesMedicineInformationService:Definition and need for medicine information service, Medicine information resources,Systematic approach in answeringmedicineinformation queries, Preparation of verbaland writtenresponse, Establishing a drug informationcentre. PoisonInformationService:Definition,need,organizationandfunctionsofpoisoninformationcentre

12hrs

REFERENCEBOOKS:

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – ParthasarathiG,KarinNyfort-HansenandMilapNahata
2. PracticeStandardsandDefinitions-TheSocietyofHospitalPharmacistsofAustralia
3. Basicskillsininterpretinglaboratorydata-ScottLT,AmericanSocietyofHealthSystemPharmacistsInc
4. Relevantreviewarticlesfromrecentmedicalandpharmaceuticalliterature

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PHARMACOTHERAPEUTICS-I(MPP102T)

THEORY **60Hours**

Scope: This course aims to enable the students to understand the different treatmentapproaches in managing various disease conditions. Also, it imparts knowledge andskills in optimizing drug therapy of a patient by individualizing the treatment planthroughevidence-basedmedicines.

Objectives

Uponcompletionofthiscourseitisexpectedthatstudentsshallbeableto:Describeandexplai

- ntherationalefordrugtherapy
- Summarizethetherapeuticapproachformanagementofvariousdiseaseconditionsinclu dingreference tothelatestavailable evidence
- Discusstheclinicalcontroversiesindrugtherapyandevidencebasedmedicine
- Prepareindividualizedtherapeutic plans basedondiagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, andmonitoring therapy (including alternatives, time- course of clinical andlaboratoryindicesoftherapeuticresponse andadverseeffect/s)

Etiopathogenesisandpharmacotherapyofdiseasesassociatedwithfollowingsystems

Unit-1:Cardiovascularsystem:Hypertension,Congestivecardiacfailure,Acutecoronary syndrome,Arrhythmias,Hyperlipidemias.

Unit-2-Respiratorysystem:Asthma,Chronicobstructiveairwaysdisease,Druginduced pulmonarydiseasesEndocrine system:Diabetes,Thyroiddiseases

Unit-3:Gastrointestinalsystem:Pepticulcerdiseases,Refluxesophagitis,Inflammatory boweldiseases,Jaundice&hepatitis

Unit-4:Gastrointestinalsystem:Cirrhosis,DiarrheaandConstipation,Drug-inducedliver disease, Hematological diseases: Anemia, Deep vein thrombosis, Drug inducedhematologicaldisorders

Unit-5:Boneandjointdisorders:Rheumatoidarthritis,Osteoarthritis,Gout,Osteoporosis

DermatologicalDiseases:Psoriasis,Eczemaandscabies,impetigo,druginducedskin disordersOphthalmology:Conjunctivitis,Glaucoma

REFERENCEBOOKS:

1. RogerandWalker.ClinicalPharmacyandTherapeutics-ChurchillLivingstonepublication

2. JosephT.Dipiroet al.Pharmacotherapy:APathophysiologicApproach-Appleton&LangeRobinsSL.Pathologicbasisofdisease-W.B.Saunderspublication

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HOSPITAL&COMMUNITY PHARMACY(MPP103T)

THEORY **60Hours**

Scope:Thiscourseisdesignedtoimpart basicknowledgeandskillsthat arerequired to practice pharmacy in both hospital and community settings**Objectives**

Uponcompletionofthiscourseitisexpectedthatstudentsshallbeableto:Underst

- andtheorganizationalstructureofhospitalpharmacyUnderstanddrugpolicy
- anddrugcommitteesKnowaboutprocurement&drugdistributionpractices
- Know the admixtures of
- radiopharmaceuticalsUnderstand the community
- pharmacy managementKnowaboutvalueaddedservicesincommunit ypharmacies

Unit-1:IntroductiontoHospitals– Definition,classification,organizationalstructureHospitalPharmacy:Definition, Relationshipofhospitalpharmacydepartment withotherdepartments, Organizational structure, legal requirements, work load statistics,Infrastructural requirements, Hospital Pharmacy Budget and Hospital Pharmacymanagement HospitalDrugPolicy:Pharmacy&TherapeuticsCommittee,InfectionControlcommittee,R esearch&EthicsCommittee,ManagementofMedicines asper NABH. **12hrs**

Unit-2 : Hospital FormularyGuidelines and its development, Developing Therapeuticguidelines, Drug procurement process, and methods of Inventory control, Methods ofDrugdistribution, Intravenousadmixtures,HospitalWasteManagement. **12hrs**

Unit-3: Education and training: Training of technical staff, training and continuingeducationforpharmacists,Pharmacystudents,Medicalstaffandstudents,Nursingsta ff andstudents, Formal and informal meetings and lectures, Drug and therapeuticsnewsletter.Community Pharmacy Practice: Definition, roles & responsibilities ofcommunitypharmacists,andtheirrelationship withotherhealthcareproviders.

Community Pharmacymanagement:Legal requirementsto start communitypharmacy,siteselection, layout &design,drugdisplay,superdrugstoremodel,accounts andaudits, Good dispensing practices, Different softwares & databases used in communitypharmacies. Entrepreneurshipincommunitypharmacy **12Hrs**

Unit-4:Prescription–Legalrequirements&interpretation,prescriptionrelatedproblems Responding to symptomsofminorailments:Headache, pyrexia, menstrual pains, foodand drug allergy, OTC medication: Rational use ofoverthe counter medicationsMedicationcounselinganduseofpatient informationleafletsMedicationadherence–Definition, factors influencing adherence behavior, strategies to improve medicationadherencePatientreferralstothedoctors,ADRmonitoringincommunityphar macies.

12 hrs

Unit-5:HealthPromotion– Definitionandhealthpromotionactivities,familyplanning,Healthscreeningservices,first aid,preventionofcommunicableandnon-communicablediseases, smoking cessation, Child & mother care NationalHealthPrograms-RoleofCommunityPharmacistin Malaria and TB control programs Home Medicines reviewprogram – Definition, objectives, Guidelines, method and outcomes Research incommunitypharmacyPractice . **12hrs**

REFERENCEBOOKS:

1. HospitalPharmacy-HassanWE.LeaandFebigerpublication.
2. Textbookofhospitalpharmacy-AllwoodMCandBlackwell.
3. Avery'sDrugTreatment,AdisInternationalLimited.
4. CommunityPharmacyPractice–RameshAdepu,BSPPublishers,Hyderabad
5. RemingtonPharmaceuticalSciences

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CLINICALRESEARCH (MPP104T)

THEORY **60Hours**

Scope: This course aims to provide the students an opportunity to learn drug developmentprocessespeciallythephasesofclinicaltrialsandalsotheethicalissues involved intheconduct ofclinicalresearch.Also,itaimstoimpartsknowledgeanddevelopskillsonconceptualizing,designing,conductingandmanagingclinicaltrials

Objectives

Uponcompletionofthiscourseitisexpectedthatstudentsshallbeableto:Knowt
⌐he newdrugdevelopmentprocess.
⌐Understandtheregulatoryandethicalrequirements.Ap
⌐preciate and conduct the clinical trials
⌐activitiesKnowsafetymonitoringandreportinginclini
⌐caltrialsManage thetrialcoordinationprocess

Unit-1: Drug development process: Introduction, variousapproachesto drug discovery,Investigationalnewdrugapplicationsubmission EthicsinBiomedicalResearch: EthicalIssues in Biomedical Research – Principles of ethics in biomedical research, Ethicalcommittee [institutional review board] - its constitution and functions, Challenges inimplementation of ethical guidelines, ICH GCP guidelines and ICMR guidelines inconductofClinicaltrials,DrugSafetyReporting. **12Hrs**

Unit-2:TypesandDesignsused inClinicalResearch:Planningandexecutionofclinical trials,Various Phases of clinical trials, Bioavailability and Bioequivalence studies,Randomization techniques (Simple randomization, restricted randomization, blockingmethod and stratification), Types of research designs based on Controlling Method(Experimental, Quasi experimental, and Observational methods) Time Sequences(Prospective and Retrospective), Sampling methods (Cohort study, case Control studyand cross sectional study), Health outcome measures (Clinical & Physiological,Humanisticand economic) ClinicalTrialStudyteam:Rolesand responsibilitiesof:Investigator, StudyCoordinator,Sponsor,Monitor,ContractResearchOrganization

12hrs

Unit-3: Clinical trial Documents: Guidelines to the preparation of following documents:Protocols,Investigator'sBrochure,InformedConsentForm,Casereportforms,Contracts andagreements,DairyCards
ClinicalTrialStartupactivities:SiteFeasibilityStudies,Site/Investigatorselection, Pre-studyvisit,Investigatormeeting, Clinical trial agreement execution,

Ethicscommitteedocumentpreparationandsubmission. **12Hrs**

Unit-4:InvestigationalProduct:ProcurementandStorageofinvestigationproductFilingprocedures: Essentialdocumentsforclinicaltrial,TrialMasterFilepreparationandmaintenance,InvestigatorSiteFile,PharmacyFile,Siteinitiationvisit,Conduct,ReportandFollowup ClinicalTrialMonitoringandCloseout:Preparationandconductofmonitoringvisit:Reviewofsourcedocuments,CRF,ICF,IPstorage,accountabilityandreconciliation,StudyProcedure,ECcommunications,Safetyreporting,Monitoringvisitreportingandfollow-upClose-Outvisit:Studyrelateddocumentscollection,Archivalrequirement,InvestigationalProductreconciliationanddestruction, Close-Outvisit report. **12hrs**

Unit-5:QualityAssuranceandQualityControlin Clinical Trials: Types ofaudits,Audit criteria,Auditprocess,Responsibilitiesofstakeholdersinaudit process,Audit follow-upanddocumentation,AuditresolutionandPreparingforFDAinspections,Fraudandmisconductmanagement

DataManagementInfrastructure and System Requirement for DataManagement: Electronic data capture systems, Selection and implementation of newsystems, System validation and test procedures, Coding dictionaries, Data migration andarchival Clinical Trial Data Management: Standard Operating Procedures, Datamanagementplan,CRF&Databasedesignconsiderations,Studyset-up,Dataentry,CRFtrackingandcorrections,Datacleaning,ManaginglaboratoryandADRdata, Datatransferand database lock, QualityControland Quality Assurance in CDM, Data mining andwarehousing **12 hrs**

REFERENCEBOOKS:

1. Principlesandpracticeofpharmaceuticalmedicine,Secondedition.Authors:Lionel.D.Edward,Aadrew.J.FletherAnthonyWFos,PeterDSloaierPublisher:Wiley;
2. Handbookofclinicalresearch.JuliaLloydand AnnRavenEd.ChurchillLivingstone
3. PrinciplesofClinicalResearcheditedbyGiovannadiIgnazio,DiGiovannaandHaynes.
4. Central Drugs Standard Control Organization. Good Clinical Practices- Guidelines forClinicalTrialsonPharmaceuticalProductsinIndia.New Delhi:MinistryofHealth.
5. International Conference on Harmonisation of Technical requirements for registration ofPharmaceuticalsforhuman use.ICH HarmonisedTripartite Guideline.Guideline forGoodClinicalPractice.E6;May1996.
6. EthicalGuidelinesforBiomedicalResearchonHumanSubjects.IndianCouncilofMedicalResearch,NewDelhi.
7. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, JohnWileyandSons.
8. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. SecondEdition,Jan2000,WileyPublications.
9. Goodman&Gilman:JGHardman,LELimbard,McGrawHillPublications.

Relevantreviewarticlesfromrecentmedicalandpharmaceuticalliterature

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PHARMACYPRACTICE PRACTICAL–I(MPP105P)

Thestudentsarerequiredtobepostedtovariousclinicalwardsfortheirexposurewiththerapeutic management and other clinicalaspects. Theyare expected to have experience and do atutorial as well as case presentation in the following clinical conditions. The students have tomake at least 10 case presentations covering most common diseases found in the hospital towhich the college is attached. The student should also submit a record of the cases presented.Thelist of clinical cases presented should include follow-up of the clinical cases mentioned belowfrom the day of admission till discharge and presented in the SOAP (Subjective, Objective,AssessmentandPlan)format.

1. TreatmentChartReview(one)
2. MedicationHistoryInterview(one)
3. PatientMedicationCounseling(two)
4. DrugInformationQuery(two)
5. PoisonInformationQuery(one)
6. LabDataInterpretation(two)
7. ABCAnalysisofagivenlistofmedications(one)
8. Preparation ofcontentofamedicine,withproperjustification,fortheinclusioninthe hospitalformulary(one)
9. Formulationanddispensingofagivenlvadmixtures(one)

REFERENCEBOOKS

1. RogerandWalker.ClinicalPharmacyandTherapeutics–ChurchillLivingstonepublication
2. JosephT.Dipiroetal.Pharmacotherapy:APathophysiologicApproach-Appleton&Lange
3. RobinsSL.Pathologicbasisofdisease-W.B.Saunderspublication
4. EricT.Herfindal.ClinicalPharmacyandTherapeutics-WilliamsandWilkinsPublication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinicalUse ofDrugs-LippincottWilliams andWilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro.PharmacotherapyPrinciplesandpractice—McGrawHillPublication

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PHARMACYPRACTICEPRACTICAL–II (MPP106P)

Thestudentsarerequiredtobepostedtovariousclinicalwardsfortheirexposurewiththerapeutic management and other clinicalaspects. Theyare expected to have experience and do atutorial as well as case presentation in the following clinical conditions. The students have tomake at least 10 case presentations covering most common diseases found in the hospital towhich the college isattached.Thestudentshouldalsosubmitarecordofthecasespresented.Thelistofclinicalcasespresentedshouldincludefollow-upof theclinical casesmentionedbelowfrom theday ofadmission till discharge and presented in the SOAP (Subjective, Objective, Assessment andPlan)format.

1. Presentation of clinical cases of various disease conditions adopting Pharmaceutical CarePlanModel(eight).The casesmaybe selectedfromthefollowingWards:
   - Gastroenterology
   - Cardiology
   - Pulmonology
   - Orthopedics
   - Endocrinology
   - Dermatology
2. Preparationofapatientinformationleaflet(two)
3. PreparationofStudyProtocol(one)
4. PreparationofInformedConsentForm(one)

REFERENCEBOOKS

1. PracticeStandardsandDefinitions-TheSocietyofHospitalPharmacistsofAustralia
2. ThomasJJohnson,CriticalCarePharmacotherapeutics
3. CollenDL,SnehaBS,FundamentalSkillsforPatientCareinMPP
4. PatientAssessmentinPharmacy,byYolandaMH
5. Relevantreviewarticlesfromrecentmedicalandpharmaceuticalliterature

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SEMESTER-II
PRINCIPLESOFQUALITYUSEOFMEDICINES(MPP201T)

THEORY **60Hours**

Scope: This course is designed to impart basic knowledge and skills that are required to practicequalityuseofmedicines(QUM)indifferenthealthcaresettingsandalsotopromotequalityuseof medicines,inclinicalpractice,throughevidence-basedmedicine approach.

Objectives:

Uponcompletionofthiscourseitisexpectedthatstudentsshallbeableto:Understandthe

- principles of quality use of
- medicinesKnowthebenefitsandrisksassociatedwithuseofmedicines
- Understandregulatoryaspects ofqualityuse
- ofmedicinesIdentifyandresolvemedicationrelatedproblem
- sPromote qualityuseofmedicines
- Practiceevidence-basedmedicines

Unit-1:Introductionto Qualityuseofmedicines(QUM):DefinitionandPrinciplesofQUM, Keypartnersandresponsibilitiesofthepartners,BuildingblocksinQMC,Evaluationprocessin QMC,CommunicationinQUM,Costeffectiveprescribing. **12 hrs**Unit-2:ConceptsinQUMEvidencebasedmedicine:Definition,conceptofevidencebased medicine,ApproachandpracticeofevidencebasedmedicineinclinicalsettingsEssentialdrugs:Defin ition,need,conceptofessentialdrug,Nationalessentialdrugpolicyandlist. Rationaldruguse:Definition,conceptandneedforrationaldruguse,Rationaldrugprescribing,Roleof pharmacistinrationaldruguse. **12 hrs**

Unit-3:QUMinvarioussettings:Hospitalsettings,Ambulatorycare/Residentialcare,Roleofhealthcareprofe ssionalsin promoting the QUM, Strategiesto promotetheQUM, Impact of QUMonE-health,integrativemedicineandmultidisciplinarycare.QUMinspecialpopulation:Pediatricprescribin g,Geriatricprescribing,Prescribinginpregnancyandlactation,Prescribinginimmunecompromisedan dorganfailurepatients. **12hrs**

Unit-4: Regulatory aspects of QUM in India: Regulation including scheduling, Regulation ofcomplementarymedicines,RegulationofOTCmedicines,Professionalresponsibilityofpharmacist, RoleofindustryinQUMinmedicinedevelopment. **12hrs**

Unit-5: Medication errors: Definition, categorization and causes of medication errors, Detectionand prevention of medication errors, Role of pharmacistin monitoring and managementofmedicationerrorsPharmacovigilance: Definition, aims andneedforpharmacovigilance,Types,predisposingf actorsandmechanismofadversedrugreactions(ADRs),Detection,reportingandmonitoringofADRs, CausalityassessmentofADRs,ManagementofADRs, Roleofpharmacistinpharmacovigilance. **12hrs**

REFERENCEBOOKS:

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – ParthasarathiG,KarinNyfort-HansenandMilapNahata
2. AndrewsEB,MooreN.Mann'sPharmacovigilance
3. DipiroJT,TalbertRL,YeeGC.Pharmacotherapy:APathophysiologicApproach
4. StrausSE,RichardsonWS,GlasziouP,HaynesRB.Evidence-BasedMedicine:Howtopracticeandteachit
5. CohenMR.MedicationErrors

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PHARMACOTHERAPEUTICSII (MPP202T)

THEORY **60Hours**

Scope: This course aims to enable the students to understand the different treatmentapproaches in managing variousdisease conditions. Also, it impartsknowledge and skillsin optimizing drug therapy of a patient by individualizing the treatment plan throughevidence-basedmedicines.

Objectives

Uponcompletionofthiscourseitisexpectedthatstudentsshallbeableto:

- Describeandexplaintherationalefordrugtherapy
- Summarize the therapeutic approach for management of various disease conditionsincludingreference tothelatestavailable evidence
- Discusstheclinicalcontroversiesindrugtherapyandevidencebasedmedicine
- Prepareindividualizedtherapeuticplansbasedondiagnosis
- Identifythepatientspecificparametersrelevantininitiatingdrugtherapy,andmonitoring therapy(including alternatives, time- courseofclinicaland laboratoryindices oftherapeutic responseandadverseeffect/s

Unit-1: Nervous system: Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer'sdisease, NeuralgiasandPainpathwaysandPainmanagement. **12hrs**

Unit-2:Psychiatricdisorders:Schizophrenia,Depression,Anxietydisorders,Sleepdisorders, Drug induced psychiatric disorders Renal system: Acute renal failure, Chronicrenalfailure, Renaldialysis,Druginducedrenaldisease **12hrs**

Unit-3: Infectious diseases: General guidelines for the rational use of antibiotics andsurgicalprophylaxis,Urinarytractinfections,Respiratorytractinfections,Gastroenteritis, Tuberculosis,Malaria,Bacterialendocarditis,Septicemia. **12hrs**

Unit-4:Infectiousdiseases:Meningitis,HIVandopportunisticinfections,Rheumaticfever,Dengue fever,H1N1,Helmenthiasis,FungalinfectionsGynecologicaldisorders:Dysmenorrhea,Hormone replacementtherapy. **12hrs**

Unit-5:Oncology:Generalprinciplesofcancerchemotherapy,pharmacotherapyofbreastcancer, lung cancer, head & neck cancer, hematological malignancies, Management ofnauseaandvomiting,Palliativecare **12hrs**

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REFERENCEBOOKS

1. RogerandWalker.ClinicalPharmacyandTherapeutics-ChurchillLivingstonepublication.
2. JosephT.Dipiroetal.Pharmacotherapy:APathophysiologicApproach-Appleton&Lange
3. RobinsSL.Pathologicbasisofdisease-W.B.Saunderspublication
4. EricT.Herfindal.ClinicalPharmacyandTherapeutics-WilliamsandWilkinsPublicationLloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs-LippincottWilliams andWilkins

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CLINICALPHARMACOKINETICSANDTHERAPEUTICDRUGMONITORING (MPP203T)

THEORY **60Hours**

Scope:

This course is designed to enable students to understand the basics principles and applications ofpharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drugconcentration profilein alteredpharmacokinetics,drug interactionsandin therapeuticdrugmonitoringprocessestooptimizethedrugdosageregimen.Also,itenablesstudentstoun derstandthebasicconceptsofpharmacogenetics,pharmacometricsformodelingandsimulationofphar macokineticdata.

Objectives

Uponcompletionofthiscourseitisexpectedthatstudentsshallbeableto:Designthe

- drugdosage regimenforindividualpatients
- Interpretandcorrelatetheplasmadrugconcentrationswithpatients'therapeutic
- outcomesRecommenddosageadjustmentforpatientswithrenal/hepaticimpairment
- Recommenddosage adjustmentforpaediatrics
- andgeriatricsManagepharmacokineticdruginteractions
- Applypharmacokineticparametersinclinicalsettings
- Interprettheimpactofgeneticpolymorphismsofindividualsonpharmacokineticsandorpha rmacodynamics ofdrugs
- Do pharmacokinetic modeling for the given data using the principles ofpharmacometrics

Unit-1: Introduction toClinical pharmacokinetics:Compartmental and Non compartmentalmodels, Renalandnon-renalclearance, Organextractionandmodelsofhepaticclearance,Estimation and determinants of bioavailability, Multiple dosing, Calculation of loadingand maintenance doses Designing ofdosageregimens: Determination of dose and dosingintervals, Conversion from intravenous to oral dosing, Nomograms and Tabulations indesigningdosageregimen.

12hrs

Unit-2:PharmacokineticsofDrugInteraction:Pharmacokineticdruginteractions, Inhibitionand Induction of Drug metabolism, Inhibition of Biliary Excretion Pharmacogenetics:Genetic polymorphisminDrugmetabolism: CytochromeP-450Isoenzymes,GeneticPolymorphism inDrug Transport and DrugTargets, Pharmacogenetics and Pharmacokinetic / Pharmacodynamic considerationsIntroductiontoPharmacometrics:IntroductiontoBayesianTheory, AdaptivemethodorDosingwith feedback,AnalysisofPopulationpharmacokineticData.

12hrs

Unit-3:Non Linier Mixed Effects Modelling: The Structural or Base Model, ModelingRandom Effects, Modeling Covariate Relationships, Mixture Model, EstimationMethods,ModelBuildingTechniques,CovariateScreeningMethods,Testingthem odelassumptions,Precisionoftheparameterestimatesandconfidenceintervals,Modelmisspeci fication and violation of the model assumptions, Model Validation, Simulationofdosing regimensand dosingrecommendations,Pharmacometricssoftware.**12hrs**

Unit-4:AlteredPharmacokinetics:Drugdosingintheelderly,Drugdosinginthepaediatrics, Drug dosing in the obese patients, Drug dosing in the pregnancy andlactation,Drug dosing in the renal failure and extracorporeal removal of drugs, Drug dosing in theinhepaticfailure. **12hrs**

Unit-5:TherapeuticDrugmonitoring:Introduction,Individualizationofdrugdosage regimen(Variability – Genetic,age,weight,disease and Interacting drugs),Indications for TDM,Protocol for TDM,
Pharmacokinetic/PharmacodynamicCorrelationindrugtherapy,TDMofdrugsusedinthefollo wingconditions:Cardiovasculardisease: Digoxin,Lidocaine, Amiodarone; Seizure disorders:
Phenytoin,Carbamazepine,SodiumValproate;Psychiatricconditions:Lithium,Fluoxetine,A mitriptyline;
Organtransplantations:Cyclosporine;CytotoxicAgents:Methotrexate,5-FU,
Cisplatin;
Antibiotics:Vancomycin,Gentamicin,Meropenem **12 hrs**

REFERENECEBOOKS:

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics &Pharmacokinetics.NewYork:McGrawHill.
2. PeterL.Bonate.Pharmacokinetic-PharmacodynamicModelingandSimulation.Springer Publications.
3. Michael E.Burton,Leslie M.Shaw,Jerome J.Schentag,William E.Evans.AppliedPharmacokinetics&Pharmacodynamics:Principlesof TherapeuticDrugMonitoring.IippincottWilliams&Wilkins.
4. Steven How-YanWong,IrvingSunshine.Handbook of Analytical Therapeutic DrugMonitoringandToxicology.CRCPress,USA.
5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London:PharmaceuticalPress.
6. JosephT.Dipiro,WilliamJ.Spruill,WilliamE.Wade,RobertA.BlouinandJaneM.Pruemer .Concepts in Clinical Pharmacokinetics. American Society of Health-SystemPharmacists,USA.
7. MalcolmRowland, Thomas N. Tozer.ClinicalPharmacokinetics and pharmacodynamics:conceptsandapplications.IippincottWilliams&Wilkins,USA.
8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health systemPharmacists,USA.

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9. MichaelE.Winter.BasicClinicalPharmacokinetics.lippincottWilliams&Wilkins,USA.
10. MiloGibaldi.BiopharmaceuticsandClinicalPharmacokinetics.PharmaBookSyndicate,US A.
11. DhillonandKostrzewski.Clinicalpharmacokinetics.PharmaceuticalPress,London.
12. JohnE .Murphy. ClinicalPharmacokinetics. 5thedition. US:AmericanSocietyofHealth-System Pharmacist,
USA.Relevantreviewarticlesfromrecentmedicalandpharmaceuticalliterature

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PHARMACOEPIDEMIOLOGY&PHARMACOECONOMICS(MPP204T)

THEORY **60Hours**

Scope: Thiscourseenablesstudents tounderstandvariouspharmacoepidemiologicalmethods andtheirclinical applications.Also,itaims toimpartknowledge on basicconcepts, assumptions, terminology, and methods associated with Pharmacoeconomicsand health related outcomes, and when should be appropriate Pharmacoeconomic modelshouldbeappliedfora healthcare regimen.

Objectives

Uponcompletionofthiscourseitisexpectedthatstudentsshallbeableto:Unders
- tandthe variousepidemiologicalmethodsandtheirapplicationsUnderstand
- thefundamentalprinciplesofPharmacoeconomics.
- Identifyanddeterminerelevantcostandconsequencesassociatedwithpharmacyproducts andservices.
- PerformthekeyPharmacoeconomicsanalysismethodsUnderstandthePharmacoeconomicd
- ecisionanalysismethodsanditsapplications.DescribecurrentPharmacoeconomicmethods
- andissues.
- UnderstandtheapplicationsofPharmacoeconomicstovariouspharmacysettings.

Unit-1: Introduction to Pharmacoepidemiology:Definition,Scope, Need, Aims & Applications;Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number ofprescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis andTherapysurveys,Prevalence,Incidencerate,Monetaryunits,numberofprescriptions,unitofdrugsdispensed,defineddailydosesandprescribeddailydoses,medicationsadherencemeasurements.
Concept of risk: Measurement of risk, Attributable risk and relative risk, Time-riskrelationshipandoddsratio. **12hrs**

Unit-2: Pharmacoepidemiological Methods: Qualitative models: Drug Utilization Review;Quantitativemodels:casereports,caseseries,Crosssectionalstudies,Cohortandcasecontrolstudies, Calculation of Odds' ratio, Meta analysis models, Drug effects study in populations:Spontaneous reporting, Prescription event monitoring, Post marketing surveillance,.Recordlinkagesystems, ApplicationsofPharmacoepidemiology **12hrs**

Unit-3: Introductionto Pharmacoeconomics: Definition, historyofPharmacoeconomics, Need ofPharmacoeconomic studiesinIndianhealthcaresystem.
Cost categorization and resources forcostestimation:Directcosts. Indirectcosts. Intangiblecosts.OutcomesandMeasurementsofPharmacoeconomics:Typesofoutcomes:Clinicaloutcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, DisabilityAdjusted Life Years Incremental Cost Effective Ratio, Average Cost Effective Ratio. PersonTime,WillingnessTo Pay,TimeTradeOffandDiscounting. **12hrs**

Unit-4: Pharmacoeconomic evaluations: Definition, Steps involved, Applications, Advantagesand disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis(CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis(CUA), CostofIllness(COI), CostConsequencesAnalysis(COA). **12hrs**

Unit-5: Definition, Steps involved, Applications, Advantages and disadvantages of thefollowing:Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, CommonHRQOL measures. Definition, Stepsinvolved, Applicationsofthe following: Decision Analysisand Decision tree, Sensitivity analysis, Markov Modeling,Software used in pharmacoeconomicanalysis,Applications ofPharmacoeconomics.**12hrs**

REFERENCEBOOKS:

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwer Lippincott Williams &Wilkins,Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley &Sons,USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health EconomicEvaluation,OxfordUniversityPress,London.
   MichaelDrummond,MarkSculpher,GeorgeTorrence,BernieO'BrienandGregStoddart.
   Methods for the Economic Evaluation of Health Care Programmes OxfordUniversityPress,London

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PHARMACYPRACTICEPRACTICAL-III(MPP205P)

The students are required to be posted to various clinical wards for their exposure withtherapeutic management and other clinical aspects. Theyare expected to have experienceand do a tutorial as well as case presentation in the following clinical conditions. Thestudents have to make at least 10 case presentations covering most common diseasesfound in the hospital to which the college is attached. The student should also submit arecord of the cases presented. The list of clinical cases presented should include follow-up of the clinical cases mentioned below from the day of admission till discharge andpresentedintheSOAP (Subjective,Objective,Assessmentand Plan)format.

ListofExperiments(12)

1. Causalityassessmentofadversedrugreactions(three)
2. Detectionandmanagementofmedicationerrors(three)
3. CalculationofBioavailabilityandBioequivalencefromthegivendata(two)
4. InterpretationofTherapeuticDrugMonitoringreportsofagivenpatient(two)
5. Assessmentofdruginteractionsinthegivenprescriptions
6. Answeringdruginformationquestions

REFERENCEBOOKS:

1. RogerandWalker.ClinicalPharmacyandTherapeutics–ChurchillLivingstonepublication.
2. JosephT.Dipiroetal.Pharmacotherapy:APathophysiologicApproach-Appleton&Lange
3. RobinsSL.Pathologicbasisofdisease-W.B.Saunderspublication
4. EricT.Herfindal.ClinicalPharmacyandTherapeutics-WilliamsandWilkinsPublication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinicalUse ofDrugs-LippincottWilliams andWilkins
6. Clinical Pharmacy and Pharmacotherapeutics by Ravi Shankar, Pharma med PressChisholm- Burns WellsSchwinghammer Malone and JosephP Dipiro.PharmacotherapyPrinciplesandpractice—McGrawHillPublication

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PHARMACYPRACTICEPRACTICAL-IV(MPP206P)

ListofExperiments(12)

1. Presentationofclinicalcasesofnervoussystemdiseasesadopting SOAP(Subjective, Objective,AssessmentandPlan)
2. Presentationofclinicalcasesofpsychiatricdisordersadopting SOAP(Subjective, Objective,AssessmentandPlan)
3. Presentationofclinicalcasesofinfectiousdiseasesadopting SOAP(Subjective, Objective,AssessmentandPlan)
4. Presentationofclinicalcasesofgynecologicaldisordersadopting SOAP(Subjective, Objective,AssessmentandPlan)
5. Presentationofclinicalcasesofcancerdiseaseadopting SOAP(Subjective,Objective,Asse ssmentandPlan)
6. Presentationofclinicalcasesofrenalsystemdisordersadopting SOAP(Subjective, Objective,AssessmentandPlan)
7. Developpharmacokineticskillsbyusing NONMEMWinNonlinsoftware.
8. Presentationofclinicalcasesofvariousdiseaseconditionsadopting PharmaceuticalCarePlan Model
9. CalculationofvariousPharmacoeconomicoutcomeanalysisforthegivendata
10. Rationaluseofmedicinesinspecialpopulationadmittedinthewards

REFERENCEBOOKS:

1. LeonShargel,SusannaWu-Pong,AndrewYu.AppliedBiopharmaceutics&Pharmacokinetics.NewYork:McGrawHill .
2. PeterL.Bonate.Pharmacokinetic-PharmacodynamicModelingandSimulation.SpringerPublications.
3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E. Evans. AppliedPharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring.IippincottWilliams&Wilkins.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of AnalyticalTherapeutic DrugMonitoringandToxicology.CRCPress,USA..
5. Joseph T. Dipiro, William J. Spruill, William E. Wade, Robert A.Blouin and Jane M.Pruemer Concepts in Clinical Pharmacokinetics. AmericanSociety of Health-SystemPharmacists,USA.

MalcolmRowland,ThomasN.Tozer.ClinicalPharmacokineticsandpharmacodynamics: conceptsandapplications.IippincottWilliams& Wilkins,USA.

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PHARMACOLOGY

(MPL)MODERNPHARMACEUTICALANALYTICALTECHNIQUES(MPL101T)

THEORY **60HOURS**

Scope

This subject deals with various advanced analytical instrumental techniques for identification,characterizationandquantificationofdrugs.InstrumentsdealtareMassspectrometer,IR, HPLC,GC etc.

Objectives

Aftercompletionofcoursestudentisabletoknow,Chemical

- sandExcipients
- Theanalysisofvariousdrugsinsingleandcombinationdosageforms Theoreticalandpractical
- skills oftheinstruments

Unit-1: a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associatedwithUV-Visible spectroscopy, Choice ofsolventsand solvent effect and ApplicationsofUV-Visible spectroscopy.

b.IRspectroscopy:Theory,ModesofMolecularvibrations,Samplehandling,Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affectingvibrationalfrequencies andApplicationsofIR spectroscopy

c. Spectroflourimetry:TheoryofFluorescence,Factorsaffectingfluorescence,Quenchers,Instrumentationand Applicationsoffluorescencespectrophotometer. **10HRS**

Unit-2:.MassSpectroscopy:Principle,Theory,InstrumentationofMassSpectroscopy,Differenttypesofionizationlikeelectronimpact,chemical,field,FABandMALDI,APCI,ESI,APPIAnalyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules,Metastableions,IsotopicpeaksandApplicationsofMassspectroscopy. **8HRS**

Unit-3.Chromatography:Principle,apparatus,instrumentation,chromatographicparameters,factorsaffecting resolutionandapplications ofthefollowing:
a)Paperchromatographyb)ThinLayerchromatographyc)Ionexchangechromatographyd)Column chromatographye)Gaschromatography f)High PerformanceLiquidchromatography g)Affinitychromatography **12HRS**

Unit-4.Electrophoresis: Principle, Instrumentation, Working conditions, factorsaffectingseparationandapplications ofthefollowing:
a) Paperelectrophoresisb)Gelelectrophoresisc)Capillaryelectrophoresisd)Zoneelectrophoresise)Movingboundaryelectrophoresisf)Isoelectricfocusing **12HRS**

Unit-5a)Immunologicalassays:RIA(Radioimmunoassay),ELISA,Bioluminescenceassays.
b) Thermaltechniques:DSC,DTA,TGA,Principle,Instrumentation,factorsaffecting,advantages anddisadvantagesandPharmaceuticalapplications. **10HRS**

Unit-6:NMRSpectroscopy:Quantumnumbersandtheirroleinnmr,Principle,instrumentation, solvent requirements in NMR, Relaxation process, NMR signals in variouscompounds.BriefoutlineofFT-NMRandC^{13}NMR,applicationsofNMRSpectroscopy. **8HRS**

REFERENCEBOOKS:

1. SpectrometricIdentificationofOrganiccompounds-RobertMSilverstein,Sixthedition,JohnWiley&Sons,2004.
2. PrinciplesofInstrumentalAnalysis-Doglas ASkoog, F. JamesHoller,TimothyA. Nieman,5thedition,Easternpress,Bangalore,1998.
3. Instrumentalmethodsofanalysis–Willards,7thedition,CBSpublishers.
4. PracticalPharmaceuticalChemistry–BeckettandStenlake,VolII,4th edition,CBS Publishers,New Delhi,1997.
5. OrganicSpectroscopy-WilliamKemp,3rdedition,ELBS,1991.
6. QuantitativeAnalysisofDrugs inPharmaceuticalformulation- PDSethi, 3rdEdition,CBSPublishers,NewDelhi,1997.
7. PharmaceuticalAnalysis-Modernmethods–PartB-JWMunson,Volume11,MarcelDekkerSeries

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ADVANCEDPHARMACOLOGY-I(MPL102T)

THEORY **60HOURS**

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacologyand to impart recent advances in the drugs used for the treatment of various diseases. Inaddition, this subject helps the students to understand the concepts of drug action andmechanismsinvolved

Objectives

Uponcompletionofthe coursethe

- studentshallbeableto:Discussthepathophysiologyandpharmacotherapyofc
- ertaindiseasesExplainthemechanismofdrugactionsatcellularandmolecula rlevel
- Understandtheadverseeffects,contraindicationsandclinicalusesofdrugsusedin treatmentofdiseases

Unit-1:GeneralPharmacology

a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation andelimination.Concepts oflinearandnon-linearcompartmentmodels.SignificanceofProteinbinding.

b. Pharmacodynamics:Mechanismofdrugactionandtherelationshipbetweendrugconcentration andeffect.Receptors,structuralandfunctionalfamiliesofreceptors,quantitationofdrug receptorsinteractionand elicited effects. **10Hrs**

Unit-2:Neurotransmission

a. Generalaspectsandstepsinvolvedinneurotransmission.
b. Neurohumoraltransmissioninautonomicnervoussystem(Detailedstudyabout neurotransmitters-AdrenalineandAcetylcholine).
c. Neurohumoraltransmissionincentralnervoussystem(Detailedstudyaboutneurotrans mitters-histamine,serotonin,dopamine, GABA,glutamateandglycine].
d. Nonadrenergicnoncholinergictransmission(NANC).Co-transmission. **10Hrs**

Unit-3:Systemicpharmacology:Adetailedstudyonpathophysiologyofdiseases,mechanismofaction,pharmacologyandtoxicology of existing as well as novel drugs used in the following systemsAutonomicPharmacologyParasympathomimeticsandlytics,sympathomimeticsandlytics,agentsaffectingneuromuscularjunction

10hrs

Unit-4: Centrel Nervous System pharmacology General andlocal anestheticsSedatives andhypnotics,drugsusedtotreatanxiety.Depression,psychosis,mania,epilepsy,neurodegenerativediseases.Narcoticandnon-narcoticanalgesics **10hrs**

Unit-5:CardiovascularPharmacology:
Diuretics,antihypertensives,antiischemics,anti-arrhythmics,drugsforheartfailureandhyperlipidemia. Hematinics, coagulants,anticoagulants, fibrinolyticsandanti- plateletdrugs

Unit-6:Autocoidpharmacology:Thephysiologicalandpathologicalroleof Histamine,Serotonin,KininsProstaglandinsOpioidautocoids.Pharmacologyofantihistamines,5HTantagonists. **10Hrs**

REFERENCEBOOKS

1. ThePharmacologicalBasisofTherapeutics,GoodmanandGillman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by DavidEGolan,ArmenH,TashjianJr,EhrinJ,Armstrong,AprilW,Armstrong,Wolters,Kluwer-LippincottWilliams &Wilkins Publishers.
3. BasicandClinicalPharmacologybyB.GKatzung
4. HandbookofClinicalPharmacokineticsbyGibaldiandPrescott.
5. AppliedbiopharmaceuticsandPharmacokineticsbyLeonShargelandAndrewB.C.Yu.
6. GrahamSmith.OxfordtextbookofClinicalPharmacology.
7. AveryDrugTreatment
8. DipiroPharmacology,Pathophysiologicalapproach.

GreenPathophysiologyforPharmacists

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PHARMACOLOGICALANDTOXICOLOGICALSCREENINGMETHODS-I(MPL 103T)

THEORY **60HOURS**

Scope: This subject is designed to impart the knowledge on preclinical evaluation of drugs andrecentexperimentaltechniquesinthedrugdiscoveryanddevelopment.Thesubjectcontenthelpsthe student to understand the maintenance of laboratoryanimals as per the guidelines, basicknowledgeofvariousin-vitroandin-vivopreclinicalevaluationprocesses

Objectives

Uponcompletionofthecoursethestudentshallbeableto,

- Appraisetheregulationsandethicalrequirementfortheusageofexperimentalanimals.
- Describethevariousanimalsusedinthedrugdiscoveryprocessandgoodlaboratory practicesinmaintenance andhandlingofexperimentalanimals
- Describethevariousnewerscreeningmethodsinvolvedinthedrugdiscoveryprocess
- Appreciateandcorrelatethepreclinicaldatatohumans

Unit-1: Laboratory Animals: Common laboratory animals: Description, handling andapplicationsofdifferentspeciesandstrainsofanimals.Transgenicanimals:Production, maintenanceand applications Anaesthesia and euthanasia of experimental animals.Maintenance and breedingof laboratory animals. CPCSEA guidelines to conduct experiments on animals Good laboratorypractice.Bioassay-Principle,scopeandlimitationsandmethods.

12hrs

Unit-2: Preclinical screening of new substances forthe pharmacological activity using in vivo, invitro,andotherpossibleanimalalternativemodels.

Generalprinciplesofpreclinicalscreening.CNSPharmacology:behavioralandmusclecoordination,CNSstimulantsanddepressants,anxiolytics,anti-psychotics,anti epilepticsandnootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiplesclerosis. DrugsactingonAutonomicNervousSystem. **12hrs**

Unit-3: Preclinical screening of new substancesforthe pharmacological activity using in vivo, invitro,andotherpossibleanimalalternativemodels.

Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. ReproductivePharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory andantipyreticagents.Gastrointestinaldrugs:antiulcer,anti-emetic,anti-diarrhealandlaxatives.

12hrs

Unit-4: Preclinical screening of new substances forthe pharmacological activity using in vivo, invitro,andotherpossibleanimalalternativemodels.
Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents.Anticanceragents.Hepatoprotectivescreeningmethods. **12hrs**

Unit-5: Preclinical screening of new substances forthe pharmacological activity usingin vivo,invitro,andotherpossibleanimalalternativemodels.Iimmunomodulators,Immunosuppressants and immunostimulants Generalprinciples of immunoassay: theoretical basis and optimization ofimmunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methodsevaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulinLimitations of animal experimentation and alternate animal experiments. Extrapolation of invitrodatato preclinicaland preclinicaltohumans. **12hrs**

REFERENCEBOOKS:

1. BiologicalstandardizationbyJ.H.BurnD.J.FinneyandI.G.Goodwin
2. ScreeningmethodsinPharmacologybyRobertTurner.A
3. EvaluationofdrugsactivitiesbyLaurenceandBachrach
4. MethodsinPharmacologybyArnoldSchwartz.
5. FundamentalsofexperimentalPharmacologybyM.N.Ghosh
6. Pharmacologicalexperimentonintactpreparationsby ChurchillLivingstone
7. DrugdiscoveryandEvaluationbyVogelH.G.
8. ExperimentalPharmacologybyR.K.Goyal.
9. Preclinicalevaluationofnewdrugsby S.K.Guta
10. HandbookofExperimentalPharmacology,SK.Kulkarni
11. PracticalPharmacologyandClinicalPharmacy,SK.Kulkarni,3rdEdition.
12. DavidR.Gross.AnimalModelsinCardiovascularResearch,2ndEdition,KluwerAcademic Publishers,London,UK.
13. ScreeningMethodsinPharmacology,RobertA.Turner.
14. RodentsforPharmacologicalExperiments,Dr.TapanKumarchatterjee.
15. PracticalManualofExperimentalandClinicalPharmacologybyBikashMedhi(Author), AjayPrakash

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CELLULAR AND MOLECULAR PHARMACOLOGY (MPL

104T)THEORY **60HOURS**

Scope:

Thesubjectimpartsafundamentalknowledgeonthestructureandfunctionsofcellularcomponentsandh elptounderstandtheinteractionofthesecomponentswithdrugs.Thisinformationwill furtherhelpthestudenttoapplytheknowledgeindrugdiscoveryprocess.

Objectives:

Uponcompletionofthecourse,thestudentshallbeable to,

•Explainthereceptorsignaltransductionprocesses.

•Explainthemolecularpathwaysaffectedbydrugs.

•Appreciatetheapplicabilityofmolecularpharmacologyandbiomarkersindrugdiscoveryprocess.

•Demonstratemolecularbiologytechniquesasapplicableforpharmacology

Unit-1:CellbiologyStructureandfunctionsofcellanditsorganelles.Genomeorganization.Geneexpressiona nditsregulation,importanceofsiRNAandmicroRNA,genemappingandgenesequencingCellcyclesan ditsregulation.Celldeath–events,regulators,intrinsicandextrinsicpathwaysofapoptosis. Necrosisandautophagy. **12hrs**

Unit-2:CellsignalingIntercellularandintracellularsignalingpathways.

Classification of receptor family and molecular structure ligand gated ion channels; G-proteincoupledreceptors,tyrosinekinase receptors andnuclearreceptors.

Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate,(IP3),NO,anddiacylglycerol.

Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway,mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer andactivatoroftranscription(STAT) signaling pathway. **12hrs**

Unit-3:Principlesandapplicationsofgenomicandproteomictools DNAelectrophoresis,PCR(reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISAandwesternblotting,RecombinantDNAtechnologyandgenetherapyBasicprinciplesofrecomb inant DNA technology-Restriction enzymes, various types of vectors. Applications ofrecombinant DNA technology. Gene therapy- Various types of gene transfer techniques, clinicalapplicationsandrecentadvances ingenetherapy. **12hrs**

Unit-4:PharmacogenomicsGenemappingandcloningofdiseasegene.Geneticvariationanditsroleinhealth/pharmacol ogyPolymorphismsaffectingdrugmetabolism

Genetic variation in drug transporters,Genetic variation in G protein coupled receptors,Applicationsofproteomicsscience:Genomics,proteomics,metabolomics,functionomics ,nutrigenomicsImmunotherapeutics,Typesofimmunotherapeutics,humanisationantibodytherapy, Immunotherapeuticsinclinicalpractice **12 hrs**

Unit-5:a.Cellculturetechniques

Basicequipmentsusedin cellculturelab.Cellculturemedia,varioustypesof cell culture,general procedure for cell cultures; isolation of cells, subculture, cryopreservation,characterizationofcellsandtheirapplication.Principlesandapplicationsof cellviabilityassays,glucose uptake assay, Calcium influx assays ,Principles and applications of flow cytometryb.Biosimilars

12hrs

REFERENCEBOOKS:

1. TheCell,AMolecularApproach.GeoffreyMCooper.
2. Pharmacogenomics:TheSearchforIndividualizedTherapies.EditedbyJ.LicinioandM -L.Wong
3. HandbookofCellSignaling(SecondEdition)EditedbyRalphA.et.al
4. MolecularPharmacology:FromDNAtoDrugDiscovery.JohnDickensonet.al
5. BasicCellCultureprotocolsbyCherilD.HelgasonandCindyL.Miller
6. BasicCellCulture(PracticalApproach)byJ.M.Davis(Editor)
7. AnimalCellCulture:

APracticalApproachbyJohnR.Masters(Editor)Currentporotocolsinmolecularbiol ogyvolItoVIeditedbyFrederickM.Ausuveletla

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PHARMACOLOGY PRACTICAL-I(MPL105P)

Listofexperiments

1. Analysisofpharmacopoeialcompoundsandtheirformulationsby UV Visspectrophotometer
2. Simultaneousestimationofmulticomponent containingformulationsbyUVspectrophotometry
3. ExperimentsbasedonHPLC
4. ExperimentsbasedonGasChromatography
5. Estimationofriboflavin/quininesulphatebyfluorimetry
6. Estimationofsodium/potassiumbyflamephotometry
7. Handlingoflaboratoryanimals.
8. Variousroutesofdrugadministration.
9. Techniquesofbloodsampling,anesthesiaandeuthanasiaofexperimentalanimals.
10. Functionalobservationbatterytests(modifiedIrwintest)
11. EvaluationofCNSstimulant,depressant,anxiogenicsandanxiolytic,anticonvulsantactivity.
12. Evaluationofanalgesic,anti-inflammatory,localanesthetic,mydriaticandmioticactivity.
13. Evaluationofdiureticactivity.
14. Evaluationofantiulceractivitybypylorusligationmethod.
15. Oralglucosetolerancetest.

REFERENCEBooks:

1. CPCSEA,OECD,ICH,USFDA,ScheduleY,EPAguidelines,
2. FundamentalsofexperimentalPharmacologybyM.N.Ghosh
3. ExperimentalPharmacologybyM.C.Prabhakar
4. HandbookofExperimentalPharmacologybyS.K.Kulkarni.
5. PracticalsinPharmacologybyR.K.Goel
6. DrugdiscoveryandEvaluationbyVogelH.G.
7. SpectrometricIdentificationofOrganiccompounds- RobertMSilverstein,
8. PrinciplesofInstrumentalAnalysis-DoglasASkoog,F.JamesHoller,TimothyA.Nieman,
9. Vogel'sTextbookofquantitativechemicalanalysis-Jeffery,Basset,Mendham,Denney,
10. BasicCellCultureprotocolsbyCherilD. HelgasonandCindyL.Mille
11. BasicCellCulture(PracticalApproach)byJ.M.Davis(Editor)
12. AnimalCellCulture:APracticalApproachbyJohnR.Masters(Editor)
13. PracticalManualofExperimentalandClinicalPharmacologybyBikashMedhi(Author), AjayPrakash(Author)Jaypeebrothers'medicalpublishersPvt.Ltd

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PHARMACOLOGYPRACTICAL-II(MPL106P)

1. IsolationandidentificationofDNAfromvarioussources(Bacteria, Cauliflower,onion, Goatliver).
2. IsolationofRNAfromyeast
3. EstimationofproteinsbyBraford/Lowry'sinbiologicalsamples.
4. EstimationofRNA/DNAbyUVSpectroscopy
5. GeneamplificationbyPCR.
6. ProteinquantificationWesternBlotting.
7. Enzymebasedin-vitroassays(MPO,AChEs,αamylase,αglucosidase).
8. Cellviabilityassays(MTT/Trypanblue/SRB).
9. DNAfragmentationassaybyagarosegelelectrophoresis.
10. DNAdamagestudybyCometassay.
11. Apoptosisdeterminationbyfluorescentimagingstudies.
12. Pharmacokineticstudiesanddataanalysisofdrugsgivenbydifferent routesofadministrationusingsoftwares
13. Enzymeinhibitionandinductionactivity
14. Extractionofdrugfromvariousbiologicalsamplesandestimationofdrugsinbiologicalfluidsusingdifferentanalyticaltechniques (UV)
15. Extractionofdrugfromvariousbiologicalsamplesandestimationofdrugsinbiologicalfluidsusingdifferentanalyticaltechniques(HPLC)

REFERENCEBOOKS:

1. CPCSEA,OECD,ICH,USFDA,ScheduleY,EPAguidelines,
2. FundamentalsofexperimentalPharmacologybyM.N.Ghosh
3. ExperimentalPharmacologybyM.C.Prabhakar
4. HandbookofExperimentalPharmacologybyS.K.Kulkarni.
5. PracticalsinPharmacologybyR.K.Goel
6. DrugdiscoveryandEvaluationbyVogelH.G.
7. SpectrometricIdentificationofOrganiccompounds- RobertMSilverstein,
8. PrinciplesofInstrumentalAnalysis-DoglasASkoog,F.JamesHoller,TimothyA.Nieman,
9. Vogel'sTextbookofquantitativechemicalanalysis-Jeffery,Basset,Mendham,Denney,
10. BasicCellCultureprotocolsbyCherilD. HelgasonandCindyL.Mille
11. BasicCellCulture(PracticalApproach)byJ.M.Davis(Editor)
12. AnimalCellCulture:APracticalApproachbyJohnR.Masters(Editor)
13. PracticalManualofExperimentalandClinicalPharmacologybyBikashMedhi(Author), AjayPrakash(Author)Jaypeebrothers'medicalpublishersPvt.Ltd

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SEMESTER-II
ADVANCEDPHARMACOLOGY-II(MPL201T)

THEORY **60Hours**

Scope

The subjectis designedtostrengthen the basic knowledgein thefieldof pharmacology andtoimpartrecentadvancesin the drugs usedfor the treatmentof various diseases.In addition, thesubjecthelpsthestudenttounderstandtheconceptsofdrugactionandmechanisminvolved**Objecti ves**

Uponcompletionofthe coursethe

Γstudentshallbeableto:Explainthemechanismofdrugactionsatcellularandmolecular

ΓlevelDiscussthePathophysiologyandpharmacotherapyofcertaindiseases

ΓUnderstandtheadverseeffects,

contraindicationsandclinicalusesofdrugsusedintreatmentofdiseases

Unit-1:EndocrinePharmacology

Molecularandcellular

mechanismofactionofhormonessuchasgrowthhormone,prolactin,thyroid,insu

linandsexhormones

Anti-

thyroiddrugs,Oralhypoglycemicagents,Oralcontraceptives,Corticosteroids.Drugsaffectingcalc iumregulation **12hrs**

Unit-2Chemotherapy:Cellularandmolecularmechanismofactionsandresistanceofantimicrobial agentssuchasß-

lactams,aminoglycosides,quinolones,Macrolideantibiotics.Antifungal,antiviral,andanti-TBdrugs **12hrs**

Unit-3Chemotherapy

Drugs usedin Protozoal Infections Drugs usedinthe treatment of Helminthiasis ChemotherapyofcancerImmunopharmacologyCellularandbiochemicalmediatorsofinflammationa ndimmune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma andCOPD.ImmunosuppressantsandImmunostimulants **12hrs**

Unit-4GITPharmacology

Antiulcerdrugs,Prokinetics,antiemetics,anti-diarrhealsanddrugsforconstipation andirritablebowelsyndrome.

Chronopharmacology

Biological and circadian rhythms, applications of chronotherapy in various diseases likecardiovasculardisease,diabetes,asthmaandpepticulcer **12hrs**

Unit-
5:FreeradicalsPharmacology:Generationoffreeradicals,roleoffreeradicalsinetiopathologyofvariou sdiseasessuchasdiabetes,neurodegenerativediseasesandcancer.Protective activity of certain important antioxidant : Recent Advances in
Treatment:Alzheimer'sdisease,Parkinson'sdisease,Cancer,Diabetesmellitus **12hrs**

REFEERENCEBOOKS:

1. ThePharmacologicalbasisoftherapeutics-GoodmanandGillman's
2. PrinciplesofPharmacology.ThePathophysiologicbasisofdrugtherapybyDavidEGolanetal.
3. BasicandClinicalPharmacologybyB.G-Katzung
4. PharmacologybyH.P.RangandM.M.Dale.
5. HandbookofClinicalPharmacokineticsbyGibaldiandPrescott.
6. TextbookofTherapeutics,druganddiseasemanagementbyET.HerfindalandGourley.
7. AppliedbiopharmaceuticsandPharmacokineticsbyLeonShargelandAndrewB.C.Yu.
8. HandbookofEssentialPharmacokinetics,PharmacodynamicsandDrugMetabolismforInd ustrialScientists
9. Robbins&CortanPathologicBasisofDisease,9thEd.(RobbinsPathology)
10. ACompleteTextbookofMedicalPharmacologybyDr.S.KSrivastavapublishedbyAPC AvichalPublishingCompany.
11. KD.Tripathi.EssentialsofMedicalPharmacology

Principles of Pharmacology.The Pathophysiologicbasis of drug Therapy by DavidEGolan,Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-LippincottWilliams&Wilkins Publishers

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PHARMACOLOGICALANDTOXICOLOGICALSCREENING METHODS-II
(MPL202T)

THEORY **60Hours**

Scope:

This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug &new chemical entity. This knowledge will make the student competent in regulatorytoxicologicalevaluation.

Objectives:

Uponcompletionofthecourse,thestudentshallbeableto,Explaint

Γhe various types oftoxicitystudies.

ΓAppreciatetheimportanceofethicalandregulatoryrequirementsfortoxicitystudies.

ΓDemonstratethe practicalskills requiredtoconductthepreclinicaltoxicitystudies.

Unit-1Basicdefinitionandtypesoftoxicology(general, mechanistic,regulatoryanddescriptive)

Regulatoryguidelinesforconducting toxicitystudiesOECD,ICH,EPAandScheduleY

OECD principles ofGood laboratorypractice (GLP) History, concept and its importance indrugdevelopment **12 hrs**

Unit-2Acute,sub-acuteandchronic-oral,dermalandinhalationalstudiesasperOECDguidelines.Acuteeyeirritation,skinsensitization,dermalirritation&dermaltoxicitystudies.

Testitemcharacterization-importanceandmethodsinregulatorytoxicologystudies **12hrsU**

nit-3Reproductivetoxicologystudies,Malereproductivetoxicitystudies,femalereproductivestudies(segmentIandsegmentIII),teratogenecitystudies(segmentII)Genotoxicitystudies(AmesTest,invitroandinvivoMicronucleusandChromosomal aberrationsstudies)Invivocarcinogenicitystudies **12hrs**

Unit-4:INDenablingstudies(INDstudies)-DefinitionofIND,importanceofIND,industryperspective,listofstudiesneededforINDsubmissionSafetypharmacologystudies-origin,conceptsandimportanceofsafetypharmacology.Tier1-CVS,CNSandrespiratorysafetypharmacology, HERGassay. Tier2- GI, renalandotherstudies **12hrs**

Unit-5:Toxicokinetics-Toxicokineticevaluationinpreclinicalstudies,saturationkineticsImportanceandapplicationsoftoxicokineticstudies.Alternativemethodstoanimaltoxicitytesting **12hrs**

REFERENCEBOOKS:

1. Hand book on GLP, Quality practices for regulated non-clinical research

anddevelopment(http://www.who.int/tdr/publications/documents/glp-handbook.pdf).
2. ScheduleYGuideline:drugsandcosmetics(secondamendment)rules, 2005,ministryofhealthandfamilywelfare(departmentofhealth)NewDelhi
3. DrugsfromdiscoverytoapprovalbyRickNG.
4. AnimalModelsinToxicology,3rdEdition,LowerandBryan
5. OECDtestguidelines.PrinciplesoftoxicologybyKarenE.Stine,ThomasM.Brown

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PRINCIPLES OF DRUG DISCOVERY

(MPL203T)

THEORY **60Hours**

Scope:Thesubjectimpartsbasicknowledgeofdrugdiscoveryprocess.Thisinformationwillmakethestudentcompetentindrugdiscoveryprocess

Objectives:

Uponcompletionofthecourse,thestudentshallbeableto,Explaint

Γhe various stagesofdrugdiscovery.

ΓAppreciatetheimportanceoftheroleofgenomics,proteomicsandbioinformaticsindrug

ΓdiscoveryExplainvarioustargetsfordrugdiscovery.

ΓExplainvariousleadseekingmethodandleadoptimizationAppreciatetheimportanceoftheroleofcomputeraide

Γddrugdesignindrugdiscovery

Unit-1:An overview of modern drug discovery process: Target identification, target validation,leadidentificationandleadOptimization.Economicsofdrugdiscovery.

Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role ofNucleicacidmicroarrays,Proteinmicroarrays,Antisensetechnologies,siRNAs,antisenseoligonucleotides, Zincfinger proteins. Roleoftransgenicanimals intargetvalidation.12hrs

Unit-2: Lead Identification- combinatorial chemistry& high throughput screening, in silico leaddiscoverytechniques,Assaydevelopmentforhitidentification.

Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure.Computational predictionof proteinstructure:Threadingandhomologymodelingmethods.ApplicationofNMRandX-raycrystallographyinproteinstructureprediction **12hrs**

Unit-3:RationalDrugDesign

Traditional vs rational drug design, Methods followed in traditional drug design, Highthroughputscreening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure ··

andPharmacophorebasedapproachesVirtualScreeningtechniques:Druglikenessscreening,Conceptofpharmacophoremappingandpharmacophorebasedscreening.**12hrs**

Unit-4 Molecular docking: Rigid docking, flexible docking, manual docking; Docking basedscreening.Denovodrugdesign.QuantitativeanalysisofStructureActivityRelationship

History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hanschanalysis, FeeWilsonanalysisandrelationshipbetweenthem **12hrs**

Unit-5: QSAR Statistical methods – regression analysis, partial least square analysis (PLS) andother multivariate statistical methods. 3D-QSAR approacheslike COMFA and COMSIA Prodrugdesign-Basicconcept,Prodrugstoimprovepatient acceptability,Drug solubility,Drugabsorption anddistribution,sitespecificdrugdelivery andsustaineddrugaction.Rationaleof prodrugdesignandpracticalconsiderationofprodrugdesign.

12hrs

REFERENCEBOOKS:

1. MouldySioud.TargetDiscoveryandValidationReviewsandProtocols:Volume2Emerging MolecularTargetsandTreatmentOptions.2007HumanaPressInc.
2. DarrylLeón.ScottMarkelIn. Silico TechnologiesinDrugTargetIdentificationandValidation.2006byTaylorandFrancisGroup,LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. SpringerNewYorkDordrechtHeidelbergLondon.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methodsand PrinciplesinMedicinalChemistry.PublisherWiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods andPrinciplesinMedicinalChemistry.PublisherWiley-VCH
6. Abby L .Parrill.M .Rami Reddy.RationalDrugDesign.Novel Methodology andPracticalApplications.ACSSymposiumSeries;AmericanChemicalSociety:Washington, DC,1999.

J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons,Inc.,NewJersey

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CLINICALRESEARCHANDPHARMACOVIGILANCE(MPL204T)

THEORY **60Hours**

Scope:

This subject will provide a value addition and current requirement for the students in clinicalresearchandpharmacovigilance.Itwillteachthestudentsonconceptualizing,designing,conducting, managing and reporting of clinical trials. This subject also focuses on globalscenarioof Pharmacovigilance in different methods that can be used to generate safety data. It will teachthe students in developingdrug safety data in Pre-clinical, Clinical phasesof Drug developmentandpostmarketsurveillance.

Objectives:

Upon completion of the course, the student shall be able

- to,Explaintheregulatoryrequirementsforconductingclinicaltrial
- Demonstrate the types of clinical trial
- designsExplaintheresponsibilitiesofkeyplayersinvolvedinclinica
- ltrialsExecute safety monitoring, reporting and close-out
- activitiesExplain the principles of
- PharmacovigilanceDetectnewadversedrugreactionsandtheirasse ssment
- Performtheadversedrugreactionreportingsystemsandcommunicationin Pharmacovigilance

Unit-1:RegulatoryPerspectivesofClinicalTrials:

Origin and Principles of International Conference on Harmonization - Good Clinical Practice(ICH-GCP)guidelinesEthicalCommittee:InstitutionalReviewBoard,EthicalGuidelinesforBiomedicalResearchandHumanParticipant-Schedule Y,ICMR

InformedConsentProcess:StructureandcontentofanInformedConsentProcessEthicalprinciplesgoverning informedconsentprocess **10hrs**

Unit-2:ClinicalTrials: Typesand DesignExperimentalStudy-RCTand NonRCT,ObservationStudy:Cohort,CaseControl, CrosssectionalClinicalTrialStudyTeam RolesandresponsibilitiesofClinicalTrialPersonnel:Investigator,StudyCoordinator,Sponsor,ContractResearchOrganizationanditsmanagement. **10hrs**

Unit-3:ClinicalTrial Documentation- Guidelines to the preparation ofdocuments, Preparation ofprotocol,InvestigatorBrochure,CaseReportForms,ClinicalStudyReportClinicalTrialMonitoring-SafetyMonitoringinCT

Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity andseriousnessassessment.Predictability andpreventability assessment,Managementof adversedrugreactions;TerminologiesofADR. **10hrs**

Unit-4:

Basicaspects,terminologiesandestablishmentofpharmacovigilanceHistoryandprogressofpharmacovigilance,Significanceofsafetymonitoring,PharmacovigilanceinIndiaandinternational aspects, WHO international drug monitoring programme, WHO and Regulatoryterminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centresinHospitals,IndustryandNationalprogrammesrelatedtopharmacovigilance.Rolesandresponsibilitiesin Pharmacovigilance

10hr

Unit-5:Methods,ADRreportingandtoolsusedinPharmacovigilance

International classification of diseases, International Non- proprietary names for drugs, Passiveand Active surveillance, Comparative observational studies, Targeted clinical investigations andVaccinesafetysurveillance.SpontaneousreportingsystemandReportingtoregulatoryauthorities, GuidelinesforADRsreporting.Argus,ArisGPharmacovigilance,VigiFlow,Statisticalmethods forevaluatingmedicationsafetydata.

Unit-6:Pharmacoepidemiology,pharmacoeconomics,safetypharmacology

10hrs

REFERENCEBOOKS:

1. CentralDrugsStandardControlOrganization-GoodClinicalPractices,GuidelinesforClinicalTrialsonPharmaceuticalProductsinIndia.NewDelhi:MinistryofHealth;2001.
2. InternationalConferenceonHarmonizationofTechnicalrequirementsforregistrationofPharmaceuticalsforhuman use.ICHHarmonizedTripartite Guideline.Guidelinefor GoodClinicalPractice.E6;May1996
3. Ethical GuidelinesforBiomedical Research onHuman Subjects2000.Indian Council ofMedicalResearch,NewDelhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March2005,JohnWileyandSons
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition,Jan2000,WileyPublications

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PHARMACOLOGY PRACTICAL-III(MPL205P)

ListofExperiments

1. TorecordtheDRCofagonistusingsuitableisolatedtissuespreparation.
2. Tostudytheeffectsofantagonist/potentiatingagentsonDRCofagonistusingsuitableisolatedtissuepreparation.
3. Todeterminetothestrengthofunknownsamplebymatchingbioassaybyusingsuitabletissuepreparation.
4. Todeterminetothestrengthofunknownsamplebyinterpolationbioassaybyusing suitabletissue preparation
5. Todeterminetothestrengthofunknownsamplebybracketingbioassaybyusingsuitabletissuepreparation
6. Todeterminetothestrengthofunknownsamplebymultiple pointbioassay byusingsuitable tissuepreparation.
7. EstimationofPA2valuesofvariousantagonistsusingsuitableisolatedtissuepreparations.
8. Tostudytheeffectsofvariousdrugsonisolatedheartpreparations
9. RecordingofratBP,heartrateandECG.
10. RecordingofratECG

REFERENCEBOOKS:

1. ThePharmacologicalbasisoftherapeutics-GoodmanandGillman's
2. PrinciplesofPharmacology.ThePathophysiologicbasisofdrugtherapybyDavidEGolanetal .
3. BasicandClinicalPharmacologybyB.G-Katzung
4. PharmacologybyH.P.RangandM.M.Dale.
5. HandbookofClinicalPharmacokineticsbyGibaldiandPrescott.
6. TextbookofTherapeutics,druganddiseasemanagementbyET.HerfindalandGourley.
7. AppliedbiopharmaceuticsandPharmacokineticsbyLeonShargelandAndrewB.C.Yu.
8. HandbookofEssentialPharmacokinetics, PharmacodynamicsandDrugMetabolismforIndustrialScientists
9. ApracticalbookofPharmacologybyRameshAlluri
10. Robbins&CortanPathologicBasisofDisease,9thEd.(RobbinsPathology)AComplete TextbookofMedicalPharmacologybyDr.S.KSrivastavapublishedbyAPC AvichalPublishingCompany

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PHARMACOLOGY PRACTICAL-IV(MPL206P)

ListofExperiments

1. Drugabsorptionstudiesbyavertedratileumpreparation.
2. AcuteoraltoxicitystudiesasperOECDguidelines.
3. AcutedermaltoxicitystudiesasperOECDguidelines.
4. Repeateddosetoxicitystudies-Serumbiochemical,haematological,urineanalysis, functionalobservationtests andhistologicalstudies.
5. Drugmutagenicitystudyusingmicebone-marrowchromosomalaberrationtest.
6. Protocoldesignforclinicaltrial.(3Nos.)
7. DesignofADRmonitoringprotocol.
8. In-silicodockingstudies.(2Nos.)
9. In-silicopharmacophorebasedscreening.
10. In-silicoQSARstudies.
11. ADRreporting

REFERENCEBOOKS

1. FundamentalsofexperimentalPharmacology-byM.N.Ghosh
2. HandbookofExperimentalPharmacology-S.K.Kulakarni
3. Textbookofin-vitropracticalPharmacologybyIanKitchen
4. ExperimentalPharmacologybyM.C.Prabhakar.
5. PracticalsinPharmacologybyR.K.Goel
6. BioassayTechniquesforDrugDevelopmentbyAtta-ur-Rahman,Iqbalchoudharyand WilliamThomsen
7. AppliedBiopharmaceuticsandPharmacokineticsbyLeonShargelandAndrewB.C.Yu.
8. HandbookofEssentialPharmacokinetics,PharmacodynamicsandDrugMetabolismforIndustrial Scientists.

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PHARMACOGNOSY(MPG)

SEMESTER-I

MODERNPHARMACEUTICALANALYTICALTECHNIQUES(MIP 101T)

THEORY **60HOURS**

Scope

This subject deals with various advanced analytical instrumental techniques for identification,characterization and quantification of drugs. Instruments dealt are Mass spectrometer, IR,HPLC,GC etc.

Objectives

Aftercompletionofcoursestudentisabletoknow,Chemical

- sandExcipients
- Theanalysisofvariousdrugsinsingleandcombinationdosageforms Theoreticalandpracticals
- kills oftheinstruments

Unit-1: **10Hrs**

a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visiblespectroscopy.

b. IRspectroscopy:Theory,ModesofMolecularvibrations,Samplehandling,Instrumentationof Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrationalfrequenciesandApplications ofIR spectroscopy

c. Spectroflourimetry:TheoryofFluorescence,Factorsaffectingfluorescence,Quenchers,Instrumentationand Applications offluorescence spectrophotometer.

Unit-2: **8Hrs**

MassSpectroscopy:Principle,Theory,InstrumentationofMassSpectroscopy,Differenttypesofionizationlikeelectronimpact,chemical,field,FABandMALDI,APCI,ESI,APPIAnalyzersofQuadrupoleandTimeofFlight,Massfragmentationanditsrules,Metastableions,IsotopicpeaksandApplications ofMass spectroscopy.

Unit-3: **12Hrs**

Chromatography:Principle,apparatus,instrumentation,chromatographic parameters,factorsaffectingresolutionandapplications ofthefollowing:

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a)Paperchromatography b)ThinLayerchromatography c)Ion exchangechromatography d)Columnchromatographye)Gaschromatographyf)HighPerformanceLiquidchromatograp hyg)Affinitychromatography.

Unit-4: **10Hrs**

Electrophoresis:Principle,Instrumentation,Workingconditions,factorsaffectingseparationandappli cationsofthefollowing:

a)Paperelectrophoresisb)Gelelectrophoresisc)Capillaryelectrophoresisd)Zoneelectrophoresis e)Movingboundaryelectrophoresisf)Iso electric focusing

Unit-5: **10Hrs**

a) Potentiometry:Principle,Workinf,IonSelectiveelectrodesandapplicationsofpotentiometry.

b) Thermaltechniques:DSC,DTA,TGA,Principle,Instrumentation,factorsaffecting, advantagesanddisadvantages andPharmaceuticalapplications.

Unit-6: **8Hrs**

NMRSpectroscopy:Quantum numbersandtheirroleinNMR,Principle,instrumentation,solvent requirements in NMR, Relaxation process, NMR signals in various compounds.Briefoutline ofFT-NMR andC^{13}NMR,applicationsofNMRSpectroscopy.

REFERENCEBOOKS:

1. SpectrometricIdentificationofOrganiccompounds-RobertMSilverstein,Sixthedition, JohnWiley&Sons,2004.
2. PrinciplesofInstrumentalAnalysis-DoglasASkoog,F.JamesHoller,TimothyA.Nieman,5thedition,Easternpress,Bangalore,1998.
3. Instrumentalmethodsofanalysis–Willards,7thedition,CBSpublishers.
4. PracticalPharmaceuticalChemistry–BeckettandStenlake,VolII,4th edition,CBS Publishers,New Delhi,1997.
5. OrganicSpectroscopy-WilliamKemp,3rdedition,ELBS,1991.
6. QuantitativeAnalysisofDrugsinPharmaceuticalformulation-PDSethi,3rd Edition, CBSPublishers,NewDelhi,1997.
7. PharmaceuticalAnalysis-Modernmethods–PartB-JWMunson,Volume11,Marcel DekkerSeries

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ADVANCEDPHARMACOGNOSY-I(MPG102T)

THEORY **60HOURS**

SCOPE

Tolearnandunderstand theadvancesinthefieldofcultivationandisolationofdrugsofnaturalorigin, various phytopharmaceuticals, nutraceuticals and their medicinaluse and health benefits.**OBJECTIVES**

Uponcompletionofthecourse,thestudent shallbeableto

- knowthe,advancesinthe cultivationandproductionofdrugs
- variousphyto-pharmaceuticalsandtheirsource,itsutilizationandmedicinalvalue.
- variousnutraceuticals/herbsandtheirhealthbenefits
- Drugsofmarineorigin
- Pharmacovigilanceofdrugsofnaturalorigin

Usethebiotechnologicaltechniquesfor obtainingandinimpropvingthe qualityofthe naturalproducts/Medicinalplants

1.UNITI **10Hrs**

Abriefaccount onChemicaland Pharmacologicalaspectsand usesofthefollowingmedicinalplants-

1. **Immunomodulatorsa**.Asparagusracemosusb.Withaniasomnifera
2. **Hepatoprotectivesa**.Phyllanthusamarusb.Silybummarianum
3. **Cardioprotectivesa**.Coleusforskolin b.Alliumsativum
4. **Antivirals** a.Oreganovulgareb.Sambucusnigra
5. **Antidiabetics** a.Gymnemasylvestreb.Momordicacharantia

UNIT-II **10Hrs**

Marine natural products: General methods of isolation and purification, Study of Marine toxins,Recent advances in research in marine drugs, Problems faced in research on marine drugs suchastaxonomicalidentification,chemicalscreeningandtheirsolution.

UNIT-III **10Hrs**

Nutraceuticals:

Currenttrendsandfuturescope,Inorganicmineralsupplements,Vitaminsupplements,Digestiveenzymes,Dietaryfibres,Cerealsandgrains,Healthdrinksofnaturalorigin,Antioxidants,Polyunsaturatedfattyacids,Herbsasfunctionalfoods,Formulationandstandardization neutraceuticals, Regulatoryaspects, FSSAI guidelines, Sources, name of markercompounds and their chemical nature, medicinaluses and health benefits of followingi)Spirulinaii)Soyabeaniii)Ginsengiv)Garlicv)Broccolivi)GreenandHerbal Teavii)Flax seeds viii)Blackcohoshix)Turmeric.

UNITIV:Phytopharmaceuticals:Occurrence,isolationandcharacteristicfeatures(Chemical nature,usesinpharmacy,medicinalandhealthbenefits)offollowing.

a) Carotenoids–i)αandβ-Caroteneii)Xanthophyll(Lutein)
b) Limonoids–i)d-Limoneneii)α–Terpineol
c) Saponins–i)Shatavarins
d) Flavonoids–i)Resveratrolii)Rutiniii)Hesperidiniv) Naringinv)Quercetin
e) Phenolicacids-Ellagicacid
f) Vitamins
g) TocotrienolsandTocopherols
h) Andrographolide,Glycolipids,Gugulipids,Withanolides, Vascine,Taxol
i) Miscellaneous **10hrs**

UNIT-V Secondary metabolism in tissue cultures with emphasis on production of medicinalagents- Production of Secondary metabolites from callus culture and suspension culture withemphasisonproductionofbiomedicinalslike-Ajmalicine,Shikonin,CarotenoidsandRosemarinicacid. **10hrs**

UNIT-VI

Biotransformation and Trangenesis: Biotransformation of PlantCell Culture anditsimportancein secondary metabolite production. Bioreactors for pilot and large scale cultures of plant cells.Hairyrootculturesandtheir applications. **10hrs**

REFERENCES(LatestEditionsof)

1. Pharmacognosy-G.E.TreaseandW.C.Evans.SaundersEdinburgh,NewYork.
2. Pharmacognosy-Tyler,Brady,Robbers
3. ModemMethodsofPlantAnalysis-Peach&M.V.Tracey,Vol.I&II
4. TextBookofPharmacognosybyT.E.Wallis
5. MarineNaturalProducts-Vol.ItoIV.
6. Naturalproducts:AlabguidebyRaphaelIkan,AcademicPress1991.
7. GlimpsesofIndianEthanoPharmacology,P.Pushpangadam.UlfNyman.V.George TropicalBotanic Garden&ResearchInstitute,1995.
8. Medicinalnaturalproducts(abiosyntheticapproach),PaulM.Dewick,JohnWiley&SonsLtd., England,1998.
9. ChemistryofMarineNaturalProducts-PaulJ.Schewer1973.
10. HerbalDrugIndustrybyRD.Choudhary,EasternPublisher,NewDelhi,1996.
11. CultivationofMedicinalPlantsbyC.K.Atal&B.M.Kapoor.
12. CultivationandUtilizationofAromaticPlants,C.K.Atal&B.M.Kapoor

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13.Cultivationofmedicinalandaromaticcrops,AAFarooquiandB.S.Sreeramu.UniversityPress,2001.
14. MedicinalplantbiotechnologybyCiddiVeeresham
15. PharmaceuticalsbiotechnologybyS.P.Vyas&V.K.Dixit
16. BiotechnologicalapplicationstotissueculturebyShargool,PeterD,Shargoal,CKCPress
17. NaturalProductsfromPlants,1stedition,byPeterB.Kaufman,CRCPress,NewYork,1998
18. Recent AdvancesinPhytochemistry-Vol.1&4:ScikelRuneckles-AppletonCenturycrofts.
19. TextbookofPharmacognosy,C.K.Kokate,Purohit,Ghokhale,NiraliPrakasshan,1996.
20. PharmacognosyandPharmacobiotechnology,Ashutoshkar,NewAgePublications,NewDelhi.

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PHYTOCHEMISTRY (MPG103T)

THEORY **60HOURS**

Scope: Studentsshallbeequippedwiththeknowledgeofnaturalproductdrugdiscoveryandwillbeableto isolate,identifyandextractandthephyto-constituents

OBJECTIVES

Uponcompletionofthecourse,thestudentshallbeabletoknowthe,

- differentclassesofphytoconstituents,theirbiosyntheticpathways,theirproperties,extractionandg eneralprocess ofnaturalproductdrugdiscovery
- phytochemicalfingerprintingandstructureelucidationofphytoconstituents

UNIT-I **10Hrs**

Isolation,characterizationandpurificationwithaspecialreferencetotheirimportanceinherbalindustrie soffollowingphytopharmaceuticalscontainingdrugs.

a. Alkaloids:Ephedrine,Quinine,Strychnine,Piperine,Berberine,Taxol,Vincaalkaloids
b. Glycosides:Digitoxin,Glycyrrhizin,Sennosides,Quercetin,Bacosides
c. Steroids:Hecogenin,Guggulsterone,Withanolides
d. Coumarins:Umbelliferone

UNIT-II **10Hrs**

Drug discovery and development: History of herbs as source of drugs and drug discovery, theleadstructure selection process,structure development,productdiscovery process anddrugregistration, Selection and optimization of lead compounds with suitable examples from thefollowingsource:artemesin,andrographolides.Clinicalstudiesemphasisingonphasesofclinicaltri als,protocoldesignforleadmolecules.

UNIT-III **10Hrs**

Extraction and Phytochemical studies: Recent advances in extractions with emphasis onselectionofmethodandchoiceofsolventforextraction, successiveandexhaustiveextractionandothermethodsofextractioncommonlyused like microwaveassistedextraction, Methodsoffractionation. Separation of phytoconstituents by latest CCCET, SCFE techniques includingpreparative HPLC andFlashcolumnchromatography.

UNIT_IV:Phytochemicalfingerprinting:

HPTLC and LCMS/GCMS applications in the characterization of herbal extracts. **10Hrs**

UNIT-V: Spectral (UV,IR ,NMR (1H,13C) characteristics of the following compounds

a. Carvone b).Citral c).Menthol d). Nicotine e). Kaempferol 10hrs

REFERENCEBOOKS:

1. OrganicchemistrybyI.L.FinarVol.II
2. PharmacognosybyTreaseandEvans,ELBS.
3. PharmacognosybyTylorandBrady.
4. TextbookofPharmacognosybyWallis.
5. Clark'sisolationandIdentificationofdrugsbyA.C.Mottal.
6. PlantDrugAnalysisbyWagner&Bladt.
7. Wilsonand GisvoldstextbookofOrganicMedicinnaland PharmaceuticalChemistrybyDeorge.R.F.
8. TheChemistryofNaturalProducts,EditedbyR.H.Thomson,SpringerInternationalEdn.1994.
9. NaturalProductsChemistryPracticalManualbyAneesASiddiquiandSeemiSiddiqui
10. OrganicChemistryofNaturalProducts,Vol.1&2.GurdeepRChatwal.
11. ChemistryofNaturalProducts-Vol.1onwardsIWPAC.
12. ModemMethodsofPlantAnalysis-Peach&M.V.Tracey,Vol.I&II
13. MedicinalNaturalproducts –abiosyntheticapproach, DewickPM,JohnWiley&Sons,Toronto,1998.
14. ChemistryofNaturalProducts,BhatSV,NagasampagiBA,MeenakshiS,NarosaPublishingHouse,NewDelhi.
15. Pharmacognosy&PhytochemistryofMedicinalPlants,2nd edition,BrunetonJ,InterceptLtd.,NewYork,1999

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INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY (MPG

104T)THEORY **60HOURS**

Scope:TounderstandtheIndustrialandcommercialpotentialofdrugsofnaturalorigin,integratetraditional Indian systems of medicine with modern medicine and also to know regulatory andqualitypolicyforthetradeofherbals anddrugs ofnaturalorigin.

OBJECTIVES

Bytheendofthecoursethestudentshallbeabletoknow,

•therequirementsforsettinguptheherbal/naturaldrugindustry.

•theguidelinesforqualityofherbal/naturalmedicinesandregulatoryissues.

•thepatenting/IPRofherbals/naturaldrugsandtradeofrawandfinishedmaterials.

UNIT-1 **12hrs**

Herbaldrugindustry:

a) Studyofinfrastructure,staffrequirements,projectprofile,plantandequipmentapplicabletoherbal drug industry.Plantdesign,layoutandconstruction.Pilotplantscale –uptechniques.

b) GMPandGLP

UNIT-II:Regulatoryrequirementsforsettingherbaldrugindustry:

Globalmarketingmanagement.RegulatoryrequirementsExport-Import(EXIM)policy.TRIPS : Qualityassuranceinherbal/naturaldrugproducts.ConceptsofTQM,ISO-9000.RecentguidelinesofDCGIonherbalformulations **12hrs**

UNIT-IIIMonographsofherbaldrugs:Generalparametersofmonographofherbaldrugsin AyurvedicPharmacopoeia,HerbalPharmacopoeiaandAmericanPharmacopoeia**12 hrs**

UNIT-IV: **12hrs**

Testingofnaturalproductsanddrugs:Herbalmedicines-clinicallaboratorytesting.Stabilitytestingofnaturalproducts,protocols.

UNIT:V **12hrs**

Patents: Patenting of herbaldrugs: Benefits ofpatent protection, Patent application, drafting andfilinganapplication.Indianandinternationalpatentlaws,proposedamendmentsasapplicabletoherbal/naturalproductsandprocess.Geographicalindication,Copyright,Patentablesubjectmaters,novelty,non-obviousness,utility,patentprocessingand grantofpatents

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Referencebooks

1. HerbaldrugindustrybyR.D.Choudhary(1996),EasternPublisher,NewDelhi.
2. GMPforBotanicals-RegulatoryandQualityissuesonPhytomedicinebyPulokKMukharjee(2003),IstEdition,BusinesshorizonsRobertVerpoorte,NewDelhi.
3. QualitycontrolofherbaldrugsbyPulokKMukarjee(2002),BusinessHorizonsPharmaceutical Publisher,NewDelhi.
4. PDRforHerbalMedicines(2000),MedicinalEconomicCompany,NewJersey.
5. IndianHerbalPharmacopoeia(2002),IDMA,Mumbai.
6. TextbookofPharmacognosybyC.K.Kokate,Purohit,Gokhlae(1996),NiraliPrakashan,NewDelhi.
7. TextbookofPharmacognosyand PhytochemistrybyVinod D.Rangarl (2002),PartI&II,CareerPublication,Nasik,India.
8. PlantdruganalysisbyH.WagnerandS.Bladt,Springer,Berlin.
9. StandardizationofBotanicals.Testingandextractionmethodsofmedicinalherbsby V.Rajpal (2004),Vol.I,EasternPublisher,New Delhi.
10. PhytochemicalDictionary.HandbookofBioactive CompoundsfromPlantsbyJ.B.Harborne,(1999),IIndEdition,TaylorandFrancisLtd,UK.
11. HerbalMedicine. ExpandedCommissionEMonographsbyM.Blumenthal, (2004),ISTEdition,
12. DrugFormulationManualbyD.P.S.KohliandD.H.Shah(1998),EasternPublisher,NewDelhi

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ADVANCEDPHARMACOGNOSY PRACTICAL–I (MPGI05P)

1. Extraction of Carotene from Carrot
2. Extraction of Hesperidin from orange peels
3. Extraction of Rutin from Nicotiana tobaccum
4. Isolation of Pectin from Orange peels
5. Isolation of starch from potatoes and rice
6. Isolation of Bixin from Bixa Orellana
7. Isolation of Lawsone from Henna
8. Isolation of Curcuminoids from Curcuma Longa
9. Identification of bioactive constituents from plant extracts
10. TLC studies of Phytoconstituents

Phytochemistry (MPGI06P)

1. Extraction of Glyrrhizic acid from Glycyrrhiza glabra
2. Extraction of oleo-resin from ginger
3. Isolation of the following Phytoconstituents
    a. Caffeine from Tea Leaves
    b. Caffeine from marketed product
    c. Strychnine and Brucine from Nux-Vomica by Columnchromatography.
    d. Piperine from black pepper
    e. Citric acid from Lemon
    f. Nicotine from Tobacco
4. TLC studies of Phytoconstituents
5. Estimation of phytoconstituents by various analytical methods (UV, FTIR)
6. Extraction of Quercetin from Onion using column chromatography
7. Detectionof Phytoconstituents by test tube reactions and TLC studies, such as
    a. Alkaloids,
    b. Steroids, Triterpenoids and their glycosides and saponins,
    c. Anthracene glycosides
    d. Flavanoids and their glycosides
    e. Coumarinsm
    f. Tannins
8. Identification of alkaloids in a mixture by TLC
    e.g. Atropine, Caffeine, Ergot, Piperine, Quinine, Reserpine, Strychnine andBrucine
9. Detection, extraction, and estimation of volatile oils by Clevenger's method
(Hydro distillation method), TLC of volatile oils and their pure constituents.

SEMESTER-II
ADVANCEDPHARMACOGNOSY-II(MPG201T)

THEORY **60HOURS**

SCOPE

To know and understand the Adulteration and Deterioration that occurs in herbal/natural drugsand methods of detection of the same. Study of herbal remedies and their validations, includingmethodsofscreening

OBJECTIVES

Uponcompletionofthecourse,thestudentshallbeabletoknowthe,v

Γalidationofherbalremedies

Γmethodsofdetectionofadulterationandevaluationtechniques forthe herbaldrugs methods

Γofscreeningofherbalsforvariousbiologicalproperties

Unit-1: Herbal remedies – Toxicityand Regulations: Herbals vs Conventional drugs, EfficacyofHerbalmedicineproducts,Validationofherbaltherapies,PharmacodynamicandPharmaco kineticissues. **12hrs**

Unit-2:AdulterationandDeterioration:Introduction,TypesofAdulteration/SubstitutionofHerbal drugs, Causes and Measures of Adulteration, Sampling Procedures, Determination ofForeign Matter, DNA Finger printing techniques in identification of drugs of natural origin,detection of heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs andtheir formulations. **12hrs**

Unit-3: Ethnobotanyand Ethnopharmacology: Ethnobotany in herbal drug evaluation, Impact ofEthnobotany in traditional medicine, New development in herbals, Bio-prospecting tools fordrugdiscovery,RoleofEthnopharmacologyindrug evaluation,ReversePharmacology.**12 Hrs**

Unit-4: Analytical Profiles of herbal drugs: Andrographis paniculata, Boswellia serata, Coleusforskholii,Curcumalonga,Embelicaofficinalis,Psoraleacorylifolia. **12hrs**

Unit-5: Biological screening of herbal drugs: Introduction and Need for Phyto-PharmacologicalScreening, New Strategies for evaluatingNatural Products, In vitro evaluation techniques
forAntioxidants,AntimicrobialandAnticancerdrugs.InvivoevaluationtechniquesforAnti-inflammatory,Antiulcer, Anticancer,Wound healing, Antidiabetic, Hepatoprotective, Cardioprotective,DiureticsandAntifertility,ToxicitystudiesasperOECDguidelines. **12Hrs**

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REFERENCEBOOKS:

1. GlimpsesofIndianEthanoPharmacologybyP.Pushpangadam.UlfNyman.V.GeorgeTr opicalBotanicGarden&ResearchInstitute.
2. Naturalproducts:AlabguidebyRaphaelIkan,AcademicPress.
3. Pharmacognosy-G.E.TreaseandW.C.Evans.WB.SaundersEdinburgh,NewYork.
4. Pharmacognosy-Tyler,Brady,Robbers,Lee&Fetiger.
5. ModemMethodsofPlantAnalysis-Peach&M.V.Tracey,Vol.I&II,SpringerPublishers.
6. HerbalDrugIndustrybyRD.Choudhary,EasternPublishers,NewDelhi.
7. TextbookofPharmacognosybyC.K.Kokate,Purohit,Ghokhale,NiraliPrakashan.
8. TextBookofPharmacognosybyT.E.Wallis,J&AChurchillLtd.,London.
9. QualitycontrolofherbaldrugsbyPulokKMukherjee,BusinessHorizonsPharmaceuticalP ublishers,NewDelhi.
10. IndianHerbalPharmacopoeia,IDMA,Mumbai.
11. TextbookofPharmacognosyandPhytochemistrybyVinodD.RangarI,PartI&II,CareerPublicati on,Nasik,India.
12. PlantdruganalysisbyH.WagnerandS.Bladt,2ndedition,Springer,Berlin.
13. StandardizationofBotanicals.Testingandextractionmethodsofmedicinalherbsby V.Rajpal(2004),Vol.I,EasternPublisherS,NewDelhi.
14. HerbalMedicine.ExpandedCommissionEMonographs,M.Blumenthal

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INDIANSYSTEMSOFMEDICINE (MPG203T)

THEORY **60HOURS**

SCOPE

To make the students understand thoroughlythe principles, preparations of medicines of variousIndian systems of medicine like Ayurveda, Siddha, Homeopathy and Unani. Also focusing onclinical research of traditional medicines, quality assurance and challenges in monitoring thesafetyofherbalmedicines.

OBJECTIVES

AftercompletionofthecourseStudentisabletoTounderstandthebasicprinciplesofvariousIndiansystemsofmedic ine

To knowtheclinicalresearchoftraditionalmedicines,

CurrentGoodManufacturingPracticeofIndiansystemsofmedicine andtheirformulations.

Unit-1:FundamentalconceptsofAyurveda,Siddha,UnaniandHomoeopathysystemsofmedicine Differentdosageforms oftheISM.

Ayurveda:AyurvedicPharmacopoeia,Analysisofformulationsandbiocrudedrugswithreferences to: Identity, purity and quality. Siddha: Gunapadam (Siddha Pharmacology), rawdrugs/Dhatu/JeevaminSiddhasystemofmedicine,Purificationprocess(Suddhi).**12 Hrs**

Unit-2:Naturopathy,YogaandAromatherapypractices

a) Naturopathy-Introduction,basicprinciplesandtreatmentmodalities.
b) Yoga-
IntroductionandStreamsofYoga.Asanas,Pranayama,MeditationsandRelaxationtechniq ues.
c) Aromatherapy–Introduction,aromaoilsforcommonproblems,carrieroils. **12Hrs**

Unit-3: Formulation developmentof various systemsof medicine Salient featuresofthe techniquesofpreparationofsomeoftheimportantclassofFormulationsasperAyurveda,Siddha,Homeo pathyandUnaniPharmacopoeia andtexts.Standardization,
ShelflifeandStabilitystudiesofISMformulation. **12hrs**

Unit-4:ScheduleT-GMPofIndianSystems

Components of GMP (Schedule – T) and its objectives, Infrastructural requirements, workingspace,storagearea,machineryandequipments,standardoperatingprocedures,healthandhygi ene,documentationandrecords.

Qualityassurance inISMformulation industry- GAP, GMP and GLP. Preparationofdocuments fornew drugapplicationandexportregistration.

Challengesinmonitoringthesafetyofherbalmedicines:Regulation,qualityassuranceandcontrol,Nati onal/RegionalPharmacopoeias **12Hrs**

Unit-5:

TKDL,GeographicalindicationBill,GovernmentbillsinAYUSH,ISM,CCRAS,CCRS,CCRH,CCRU. **12Hrs**

REFERENCEBOOKS:

1. AyurvedicPharmacopoeia,TheControllerofPublications,CivilLines,Govt.ofIndia,NewDelhi.
2. HandBookonAyurvedicMedicines,H. Panda,NationalInstituteofIndustrialResearch,New Delhi.
3. Ayurvedic Systemof Medicine, Kaviraj Nagendranath Sengupata, SriSatguruPublications,NewDelhi.
4. AyurvedicPharmacopoeia.FormularyofAyurvedicMedicines,IMCOPS,Chennai.
5. HomeopathicPharmacopoeia.FormularyofHomeopathicMedicines,IMCOPS,Chennai.
6. HomeopathicPharmacy:Anintroduction&Handbook,StevenB.Kayne,Churchill Livingstone,NewYork.
7. IndianHerbalPharmacopoeia,IDMA,Mumbai.
8. BritishHerbalPharmacopoeia,bRITISHHerbalMedicineAssociation,UK.
9. GMPforBotanicals-RegulatoryandQualityissuesonPhytomedicine,PulokKMukharjee,BusinessHorizons,NewDelhi.
10. IndianSystemofMedicineandHomeopathyinIndia,PlanningandEvaluationCell,Govt.ofIndia,NewDelhi.
11. EssentialofFoodandNutrition,Swaminathan,Bappco,Bangalore.
12. ClinicalDietiticsandNutrition,F.P.Antia,OxfordUniversityPress,Delhi.
13. Yoga-TheScienceofHolisticLivingbyV.K.Yoga,VivekanandaYogaPrakashnaPublishing,Bangalore

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HERBAL COSMETICS (MPG203T)

THEORY **60HOURS**

SCOPE

This subject deals with the study of preparation and standardization of herbal/natural cosmetics.This subject gives emphasis to various national and international standards prescribed regardingherbalcosmeceuticals.

OBJECTIVES

Aftercompletionofthecourse,studentshallbeableto,understandthebasicprinciplesof

- variousherbal/naturalcosmeticpreparations
- currentGoodManufacturingPracticesofherbal/naturalcosmeticsaspertheregulatoryauthorities

Unit-1:Introduction:Herbal/naturalcosmetics,Classification&Economicaspects. RegulatoryProvisionsrelationtomanufactureofcosmetics:-License,GMP,offences&Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production ofHerbal/naturalcosmetics. **12Hrs**

Unit-2: Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants,oils, colors, and some functional herbs, preformulation studies, compatibility studies, possibleinteractionsbetweenchemicalsandherbs,designofherbalcosmeticformulation.**12 hrs**

Unit-3: HerbalCosmetics : Physiologyand chemistryofskin and pigmentation, hairs, scalp, lipsand nail, Cleansing cream, Lotions,Facepowders,Facepacks,Lipsticks, Bath products, soaps andbabyproduct,Preparationandstandardisationofthe following: Tonic,Bleaches,DentifricesandMouthwashes&ToothPastes,CosmeticsforNails.**12hrs**

Unit-4:Cosmeceuticalsofherbal andnatural origin:Hairgrowthformulations,Shampoos,Conditioners, Colorants& hair oils, Fairness formulations, vanishing & foundationcreams, anti-sunburnpreparations,moisturizingcreams,deodorants. **12Hrs**

Unit-5: Analysis ofCosmetics, Toxicityscreening and test methods: Qualitycontroland toxicitystudiesasper Drugand CosmeticsAct. **12hrs**

REFERENCEBOOKS:

1. PandaH.HerbalCosmetics(Handbook),AsiaPacificBusinessPressInc,NewDelhi.
2. ThomsonEG.ModernCosmetics,UniversalPublishingCorporation,Mumbai.
3. P.P.Sharma.Cosmetics-Formulation,Manufacturing&QualityControl,Vandana Publications,NewDelhi.
4. SupriyaKB.HandbookofAromaticPlants,PointerPublishers,Jaipur.
5. SkariaP.AromaticPlants(HorticultureScienceSeries),NewIndiaPublishingAgency,New Delhi.
6. KathiKevilleandMindyGreen.Aromatheraphy(ACompleteGuidetotheHealingArt),SriSatguruPublications,New Delhi.
7. Chattopadhyay PK. Herbal Cosmetics & Ayurvedic Medicines (EOU), National InstituteofIndustrialResearch,Delhi.
8. BalsamMS&EdwardSagarin.CosmeticsScienceandTechnology,WileyInterscience,New York

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CLINICALRESEARCH AND PHARMACOVIGILANCE (MPG204T)

THEORY **60HOURS**

Scope:

This subject will provide a value addition and current requirement for the students in clinicalresearchandpharmacovigilance.Itwillteachthestudentsonconceptualizing,designing,conducting, managing and reporting of clinical trials. This subject also focuses on globalscenarioof Pharmacovigilance in different methods that can be used to generate safety data. It will teachthe students in developingdrug safety data in Pre-clinical, Clinical phasesof Drug developmentandpostmarketsurveillance.

Objectives:

Upon completion of the course, the student shall be able

- to,Explaintheregulatoryrequirementsforconductingclinicaltrial
- Demonstrate the types of clinical trial
- designsExplaintheresponsibilitiesofkeyplayersinvolvedinclinica
- ltrialsExecute safety monitoring, reporting and close-out
- activitiesExplain the principles of
- PharmacovigilanceDetectnewadversedrugreactionsandtheirasse ssment
- Performtheadversedrugreactionreportingsystemsandcommunicationin Pharmacovigilance

Unit-1:RegulatoryPerspectivesofClinicalTrials:

Origin and Principles of International Conference on Harmonization - Good Clinical Practice(ICH-GCP)guidelinesEthicalCommittee:InstitutionalReviewBoard,EthicalGuidelinesforBiomedicalResearchandHumanParticipant-ScheduleY,ICMR InformedConsentProcess:StructureandcontentofanInformedConsentProcessEthicalprinciplesgoverning informedconsentprocess **10hrs**

Unit-2:ClinicalTrials: Typesand DesignExperimentalStudy-RCTand NonRCT,ObservationStudy:Cohort,CaseControl,CrosssectionalClinicalTrialStudyTeam RolesandresponsibilitiesofClinicalTrialPersonnel:Investigator,StudyCoordinator,Sponsor,ContractResearchOrganizationanditsmanagement. **10hrs**

Unit-3:ClinicalTrial Documentation- Guidelines to the preparation ofdocuments, Preparation ofprotocol,InvestigatorBrochure,CaseReportForms,ClinicalStudyReportClinicalTrialMonitoring-SafetyMonitoring in CT, Adverse Drug Reactions: Definition and types. Detectionand reportingmethods. Severity and seriousness assessment.Predictability and preventabilityassessment, Managementofadversedrugreactions;TerminologiesofADR. **10hrs**

Unit-4:

Basicaspects,terminologiesandestablishmentofpharmacovigilanceHistoryandprogressofpharmacovigilance,Significanceofsafetymonitoring,PharmacovigilanceinIndiaandinternational aspects, WHO international drug monitoring programme, WHO and Regulatoryterminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centresinHospitals,IndustryandNationalprogrammesrelatedtopharmacovigilance.Rolesandresponsibilities inPharmacovigilance

10hr

Unit-5:Methods,ADRreportingandtoolsusedinPharmacovigilance

International classification of diseases, International Non- proprietary names for drugs, Passiveand Active surveillance, Comparative observational studies, Targeted clinical investigations

andVaccinesafetysurveillance.SpontaneousreportingsystemandReportingtoregulatoryauthorities, GuidelinesforADRsreporting.Argus,ArisGPharmacovigilance,VigiFlow,Statisticalmethods forevaluatingmedicationsafetydata.

Unit-6:Pharmacoepidemiology,pharmacoeconomics,safetypharmacology **10Hrs**

REFERENCEBOOKS:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines forClinicalTrialsonPharmaceuticalProductsinIndia. NewDelhi:MinistryofHealth;2001.

2. InternationalConferenceonHarmonizationofTechnicalrequirementsforregistrationofPharmaceuticalsforhuman use.ICH Harmonized Tripartite Guideline.GuidelineforGoodClinicalPractice.E6;May1996

3. Ethical GuidelinesforBiomedical Research onHuman Subjects2000.Indian Council ofMedicalResearch,NewDelhi.

4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March2005,JohnWileyandSons

5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition,Jan2000,WileyPublications

ADVANCED PHARMACOGNOSY-II

(MPG 205 P)

List of Experiments:

1. Preparation and standardization of any two herbal tablets
2. Estimation of total alkaloid content in herbal raw materials
3. Estimation of total flavonoid content in herbal raw materials
4. Formulation of different dosage forms and their standardization.
5. Estimation of aldehyde and ketone in volatile oils by titrimetric methods
6. Estimation of phenolic substances
7. Determination of Sennoside content in Senna leaves by colorimetric analysis
8. Determination of Withania alkaloids/steroids by colorimetric analysis
9. Determination of moisture content, heavy metals and ash values of crude drugs
10. Microscopical evaluation of organized powder crude drugs
11. Screening of herbal extracts/ products for anti microbial and antifungal
12. Screening of herbal extracts/ products for antioxidant activity by free radical scavenging methods
13. Study of analytical profile of any two plants mentioned in theory with special emphasis on marker compounds

HERBAL COSMETICS

(MPG 206 P)

1. Preparation and standardization of various simple dosage forms from Ayurvedic system.
2. Preparation of certain formulations used for Aroma therapy formulations
3. Preparation of herbal cosmetic formulation such as lipstick, herbal hair and nail care products
4. Evaluation of herbal tablets and capsules
5. Preparation of sunscreen, skin care formulations.
6. Preparation and evaluation of any two of each hair care and skin care products
7. Preparation and evaluation of poly herbal formulation face cream.
8. Preparation and evaluation of single herbal formulation face cream.
9. Preparation and evaluation of herbal ointments
10. Preparation and evaluation of herbal shampoos

PHARMACEUTICAL CHEMISTRY

MODERNPHARMACEUTICALANALYTICALTECHNIQUES (MPC101T)

THEORY **60Hours**

Scope: The appreciable knowledge will be gained by the students in the Modern AnalyticalTechniquesandcanapplythetheoriesintheAnalysisofvariousbulkdrugsandtheirformulations. The students will also be in a position to apply their knowledge in developing thenewmethods forthedeterminationandvalidatetheprocedures.

Objectives: The course is designed toimpart the knowledgein differentanalytical techniqueslike UV-Visible, IR, GC, HPLC etc so that it can be used in the analysis of bulk drugs andformulations.

UNITI **12Hours**

Introduction to chromatography and classification of chromatographic methods based on themechanismofseparation

A. Column Chromatography: Adsortion and partition, materials used for separation, solventsystem, procedureand method ofdetection. Theory, principles involved inseparation, apparatus,column materials, number of theoretical plates, elution, method of detection. Modifications likeVLC,Flash,MPLC,theiradvantage overopencolumnCC.

B. PaperChromatography: Theory,differenttechniquesemployed,filterpapersused,qualitative andquantitativedetection

UNITII **12Hours**

A. ThinLayerChromatography: Theory,principlesofseparation,apparatus,coatingmaterials, spotting, solvent systems, detection, Uses ofTLC: Finding the number ofcompounds;the class of compounds; Testing for purity/ detection of impurities; identifying compounds-Co-TLC,MixedTLC;isolatingcompounds inapureform-preparativeTLC;TwodimensionalTLC.

B. HPTLC: Theoryandprinciple,instrumentation,elutiontechniquesandpharmaceuticalapplications

C. Acomparativestudy;howisHPTLCisdifferentfromTLC,apparatus;Coatingmaterials-particle size;detection;uses.

UNITII **12Hours**

a. GasChromatography: Introduction,fundamentals,instrumentation,columns:preparation andoperation,detection;derivatization.

b. HPLCandUPLC: Principlesandinstrumentation,solventsandcolumnsusedOperationalmodes,detectionandapplications.

UNITIII **12Hours**

A. Electrophoresis:Principle,Instrumentation,Workingconditions,factors affectingseparation andapplications ofthefollowing:a) Paperelectrophoresisb)Gelelectrophoresisc)Capillary electrophoresis d)Zoneelectrophorese)Moving boundaryelectrophoresisf)Isoelectricfocusing

B. XrayCrystallography: ProductionofXrays,DifferentXraymethods,Bragg'slaw,Rotatingcrystaltech nique,Xraypowdertechnique,Typesofcrystalsandapplicationsof X-raydiffraction.

UNITIV **12Hours**

A. UV-

Visiblespectroscopy: Theoryandinstrumentationinbrief.Chromophore;Auxochrome;Types of electronic transitions; Solvent effects; Quantitative estimation of Riboflavin,Paracetamol,Diclofenac,Metronidazole,Aspirin..

B.IRspectroscopy: Theory,ModesofMolecularvibrations,Samplehandling,InstrumentationofDisp ersiveandFourier TransformIRSpectrometer,Factorsaffectingvibrationalfrequencies,Quantitative estimationofAPIsusingIRspectroscopy.

UNITV **12Hours**

A. Spectroflourimetry:TheoryofFluorescence,Factorsaffectingfluorescence,Quenchers, InstrumentationandApplicationsoffluorescence spectrophotometer.

B. FlameemissionspectroscopyandAtomicabsorptionspectroscopy: Principle, Instrumentation,InterferencesandApplications.

REFERENCES

1. SpectrometricIdentificationofOrganiccompounds-RobertMSilverstein,Sixthedition,JohnWiley&Sons,2004.
2. PrinciplesofInstrumentalAnalysis-DoglasASkoog,F.JamesHoller,TimothyA.Nieman, 5thedition,Easternpress,Bangalore,1998.
3. Instrumentalmethodsofanalysis–Willards,7thedition,CBSpublishers.
4. PracticalPharmaceuticalChemistry–BeckettandStenlake,VolII,4th edition,CBSPublishers,NewDelhi,1997.
5. OrganicSpectroscopy-WilliamKemp,3rdedition,ELBS,1991.
6. QuantitativeAnalysisofDrugsinPharmaceuticalformulation-PDSethi,3rdEdition,CBSPublishers,NewDelhi,1997.
7. PharmaceuticalAnalysis-ModernMethods–PartB-JWMunson,Vol11,Marcel.DekkerSeries
8. SpectroscopyofOrganicCompounds,2ndedn.,P.S/Kalsi,WileyesternLtd.,Delhi.
9. TextbookofPharmaceuticalAnalysis,KA.Connors,3rdEdition,JohnWiley&Sons,1982.

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ADVANCED ORGANIC CHEMISTRY–I (MPC102T)

THEORY **60Hours**

Scope: Subjectisdesignedtoprovidein-depthknowledgeaboutadvancesinorganicchemistry,differenttechniquesoforganicsynthesisand their applicationsto processchemistryaswellasdrugdiscovery.

Objectives:

Theaimofthecourseistoimpartknowledgetothestudentsof:

- Nucleophilicaliphaticsubstitution,
- lectrophilicaromaticsubstitution
- Eliminationreaction,theirmechanismandapplications.
- Knowledgeofsomenamedorganicreactions,syntheticreagentsandtheirapplication willbeimparted.
- Anotherimportantobjectiveofthecourseistointroducethestudenttothechemistryof heterocycliccompoundsasdrugs,byandlarge,haveheterocyclicrings.
-

Unit-I

Nucleophilicaliphaticsubstitution: **12Hours**

$S_N1$and$S_N2$reactions;mechanismandkinetics;structureandreactivity;stereochemistry;SN1VsSN2;roleofsolvent;substitutionVselimination;necleophilicsubstitution–alkylhalidesVsalcohols; SN1 and rearrangement; stability of carbocations, carbanions, free radicals, carbenesandnitrenes:Theirmethodofformationandsynthetic applications.

Unit-II **10Hours**

Electrophilicaromaticsubstitution:reactions;mechanism;proofforthemechanism;sulfonation – a reversible reaction; theory of reactivity; theory of orientation; orientation andsynthesis.

Unit-III **10Hours**

Elimination reactions: E1 and E2 mechanisms of alkyl halides and alcohols; evidence; E1 VsE2;elimination Vssubstitution;1,1and1,2-elimination;E1CB;Saytzeff'srule;Hofmannrule/elimination;stereochemistryofE2reactions;elimination fromalicyclic compounds.

Unit-IV **14Hours**

a) **Study of mechanism and synthetic applications of following named Reactions**:Ugireaction, Diekmann reaction, Sandmeyer reaction, Mannich reaction, Vilsmeyer-Haackreaction,Beckmannrearrangement,Friesrearrangement,Phillip'scondensationandMichaeladditionreaction.

b) SyntheticReagents&Applications:

Aluminiumisopropoxide,N-bromosuccinamide,diazomethane,dicyclohexylcarbodimide,Wittingreagent,Osmiumtetroxide,diethylazodicarboxylate,Triphenylphosphine,Lithiumaluminiumhydride, Sodiumborohydride, DCC(N,N-diacylohexylcarbodiamide)reagent.

Unit-V **14Hours**

A.Heterocylicchemistry: Structuresofheterocylic compounds;aromaticandnonaromaticheterocylces;nomenclature;

B.Five-membered ring compounds with one heteroatom: Pyrroles, Furans and Thiophenes;Aromaticity;acidity;basicity; twosyntheticmethodsforeach class; reactions; electrophillicsubstitution; reactions with acids, carbenes, nitrenes; oxidizing and reducing agents; Diels-Alderreaction;photochemicalreactions;alkylationofpyroles;metalationoffurans;reactionsofthiophe neswithnucleophiles.Comparethe reactivityofPyrroles,Furansand Thiophenes.

C. Six-memberedheterocyclicringcompoundswithoneheteroatom: Pyridines:nomenclature; physical and spectroscopic properties; tautomerism; synthetic methods; chemicalreactions–withacids,electrophilicandnucleophilicsubstitution,Diels-Alderreactions,quaternization, reaction with oxidizing and reducing agents; hetaryne formation; ring openingreactions;reactionswithfreeradicals;photochemicalreactions;theClaisenrearrangement;der ivatives of pyridine – alkyl and aryl pryidinesl halopyridines, aminopyridines, pyridine N-oxide,hydroxypyridines,pyridine aldhydesandketones

D.Synthesisofheterocycliccompounds:

Twomethodsofsynthesisandreactionsofthefollowingheterocycliccompoundsortheirderivatives; a) quinolines b) isoquinolines c) indoles d) pridazines e) pyrimidines f) pyrazines g)thiazolesh)imidazolesi)oxazoles

REFERENCES

1. "AdvancedOrganicchemistry,Reaction,MechanismsandStructure",J.March,John WileyandSons,NewYork.
2. "MechanismandStructureinOrganicChemistry",ESGould,HoldRinchartand Winston,NewYork.
3. "OrganicChemistry"Clayden,Greeves,WarrenandWoihers.,OxfordUniversityPress 2001.
4. "OrganicChemistry"VolIandII.I.L.Finar.ELBS,PearsonEducationLts,Dorling KindersleyIndiaPvt.Ltd.
5. AguidetomechanismsinOrganicChemistry,PeterSkyes(OrientLongman,New Delhi).
6. ReactiveIntermediatesinOrganicChemistry,TandomandGowel,Oxford&IBH Publishers.
7. PrinciplesofOrganicSynthesis,ROCNormanandJMCoxan,NelsonThorns.
8. OrganicSynthesis-SpecialTechniques.VKAhluwaliaandRAgarwal,Narosa Publishers.
9. OrganicReactionMechanismsIVthEdtn,VKAhluwaliaandRKParashar,Narosa Publishers.
10. HeterocyclicChemistry–J.A.Joule,K.MillsandG.F.Smith3rdEdition,CRCpress.
11. HeterocyclicChemistry–ThomasL.Gilchrist,3rdEdition,Pearsonpublications
12. HeterocyclicChemistry–RajK.Bansal,7thEdition,NewageInternationalPublishers.

ADVANCED MEDICINAL CHEMISTRY(MPC103T)

THEORY **60Hrs**

Scope:
Thesubjectisdesignedtoimpart knowledgeaboutrecent advancesinthefieldofmedicinalchemistryatthemolecularlevelincludingdifferenttechniquesforthe rationaldrugdesign.**Objective:**
Theobjectiveofthecourseistoimpartknowledgein

- Drugdiscovery
- Roleofmedicinalchemistryindrugresearch
- Differenttechniquesfordrugdiscovery
- Variousstrategiestodesignanddevelopnewdruglikemoleculesforbiologicaltargets
- Thecourseisalsoimpartsknowledgeabout different classesofdrugs,theirorigin,mechanismofaction,use,toxicityetc.

Unit-I **12Hours**

Abriefreviewofthefollowingtopics:

a. SourcesOfNewDrugs;
b. LeadsFromNaturalProducts;
c. MolecularModifications;
d. RandomScreening;
e. HighThroughtPutScreening;
f. InsilicoScreening;
g. StructuralFeaturesAndPharmacologicalAcivity;
h. Prodrugs;
i. SoftDrugs;
j. Isosterism

Unit-II **12Hours**

Anaccountoftheiroriginanddevelopment,classification,structures,mechanismofaction,SAR, usesandtoxicityof:

a. Analgesics(non-opioid)andantipyretics
b. Non-steroidalanti-inflammatoryagents
c. SynnthesisofParacetamol,Ibuprofen,Aceclofenac
d. Antidiabeticagents
e. SynnthesisofTolbutamide,Chlopropamide,Glipizide,Glimepride,Metformin
d.Screeningmethodsoftheseclasses

Unit-III **12Hours**

Anaccountoftheiroriginanddevelopment,classification,structures,mechanismofaction, SAR,usesandtoxicityof:

a. β-Adrenergicblockers
b. ACEinhibitors
c. Diuretics
d. Synthesis of Propranolol, Hydralazine, Minoxidil, Captopril, Lisinopril, Furosemide,Hydrochlorthiazide
e. H_1-receptorantagonists
f. H_2-receptorantagonists
g. Gastric-ProtonPumpInhibitors
h. SynthesisofLevocitrizine,Ranitidine,Omeprazole
i. Screeningmethodsoftheseclasses

Unit-IV **12Hours**

Anaccountoftheiroriginanddevelopment,classification,structures,mechanismofaction, SAR,usesandtoxicityof:

a. Anthihyperlipidemicagents
b. Phosphodiesteraseinhibitors
c. Quinoloneantibacterialagents.
d. Screeningmethodsoftheseclasses

Unit-V **12Hours**

Anaccountoftheiroriginanddevelopment,classification,structures,mechanismofaction, SAR,usesandtoxicity:

a. Anticanceragents
b. Antiviralagents
c. Immunosupressantsandimmunostimulatns
d. SynthesisofChlorambucil,Methotrexate,Stavudine
e. Screeningmethodsoftheseclasses

BooksRecommended:

1. Textbook of Wilson andGisvolds organicmedicinal andpharmaceutical by CharlesOwens Wilon, 12th edition , 2010, publisher: Lippincott Williams & Wilkins .Foye'sprinciplesofmedicinalchemistry
2. Burger'smedicinalchemistryanddrugdiscovery
3. Organicchemistryofsyntheticdrugs–Lednier
4. Screeningmethodsinpharmacology–RobertA.Turner.
5. DrugEvaluation–Vogel.
6. EvaluationofDrugActivities–LawrenceandBachrach.
7. MethodsinPharmacology–Swarbrick.
8. MedicinalChemistry-SurendranathPandeya,VolumeIandVolumeII
9. MedicinalChemistry-Ashutoshkar,NewAgeInternationalPublications
10. Pharmacopoeias

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CHEMISTRYOFNATURALPRODUCTS(MPC104T)

THEORY **60Hrs**

Scope:
The subject is designed to provide a detailed knowledge about chemistry, biological activity,mechanism of action, SAR, toxicity, and use of medicinal compounds of natural origin, theirsemisynthetic derivatives and development of clinically used drugs taking natural products asleads.

Objectives:
Theobjectivesofthiscoursearetoimpartknowledgetostudentsof:

- Differenttypesofnaturalcompounds,theirchemistryandmedicinalimportance.
- Hownaturalcompoundsactasdrugsperseandasleadmoleculesindrugdiscovery.
- Howstructuresareimportantforbiologicalactivityandhowachangeinstructureaffects biologicalactivity.
- Howbiotechnologyiscontributingtothedevelopmentofpharmaceuticalsofnatural origin.

UNIT-I **10Hrs**

(a) **Naturalproductsasleadsindrugdiscoveryanddevelopment:**Hownaturalproductsactedaslead moleculesindrugdiscoveryanddevelopmentwithemphasisonthesourceofthe naturalcompound, history/origin, how synthetic drugs were devoloped from them .From:

a. Salicintoaspirin
b. Quininetoantimalarials
c. Cocainetolocalanaesthetics
d. Curarealkaloidstoneuromuscularblockingdrugs.
e. Fungalmetabolitestomodernstatins
f. Snakevenomtoantihypertensives

(b) RecombinantDNAtechnologyanddrugdiscovery.

UNIT-II **10Hrs**

a. **Alkaloidsofopium:**Structureofmorphine;peripheralgroups;
modification in pheripheralgroups and effect on analgesic / biologic activity; relative potencies;opioidreceptors;endorphins andenkephalins.

b. **Ring analogues of morphine;**morphinans-levorphanol and butorphanol; benzomorphans-pentazocineandphenazociane;aminotetralins-dezocine;4-phenylpiperidines-meperidine(pethidine);4-Anilidopiperidinesorthefentanylgroup-fentanyl,alfentanyl,sufentanyl,remifentanil, lofentanil; diphenylheptanone derivatives-methadone; structures; receptoraffinities;relative potencies;advantages ofthesecompounds;structuraldifference
between4-phenyland4-anilidopiperidines.

c. **Opioidantidiarrheals-**Howstructuralmodificationof4-phenylpiperidinesandmethadoneledtothediscoveryofdiphenoxylateandloperamidestructures.Mode ofaction;usage;metabolism

ofdiphenoxylate;diphenoxin;combinationwithatropine;bindingofthesecompounds toopioidreceptor;abusepotential;use.

d. Antitissueagents(opioid)

Studyofcodeine,hydrocodonehydromorphone,noscapine, dextromethorphan, levopropoxyphene, pholcodine. Their structures, relative advantages, uses.Relationshipbetweenlevorphanolanddextromethorphan;betweenlevopropoxypheneandmethadone.

e. **Morphineantagonists**-Nalorphine,levallorphan,naloxone,naltrexone,nalmefene,cyclazocine. Structures; a comparative study of the structures of levorphanol and levallorphan,oxymorphone,naloxoneandnaltrexone,cyclazocineandpentazocine;receptoraffinities; relativeadvantages,uses.

UNIT-III **10Hours**

Anticanceragentsofnaturalorigin:

a. Anticanceragentsofplantorigin:Source;structures;descriptionofthestructuralfeatures; SAR;semisynthetic derivatives;mechanismofaction;toxicity;anduses of:

(1) Vincristineandvinblastine

(2) Podophyllotoxin

(3) Taxol

(4) Camptothecin

(b) Anticancerantibiotics:source;structures;descriptionsofthestructuralfeatures;mechanismofaction;SAR;andusesofthefollowingantibiotics :

(1) Dactinomycin

(2) Daunorubicin,doxorubicin(adriamycin),idarubicin;metabolismofdaunorubicinand doxorubicin; analogous of doxorubicin - esorubicin,epirubicin,pirarubicin,valrubicin.

(3) Abriefaccountofnogalamycin,menogaril,mithramycin,mitomycins,streptozocin

(c) Anticanceragentsfrommarineorganisms:bryostatin,dolostatin.

UnitIV **20Hours**

Steroids:

(a) **Definition**;numberingthecarbonsandlabellingtherings;somebasicsteroidskeleta;nomenclature; sterochemistry; chemical and physical properties of steroids; changes to modifypharmacokineticsproperties ofsteroids.

(b) **Sources of steroid drugs:** source and structures of cholesterol, ergosterol, stigmasterol anddiosgenin,historyofdevelopmentofsteroidindustry.Marker'ssynthesis.

(c) **Steroidalantiinflammatoryagents:**structures;SAR;routesof administration;mainpharmacologiceffects-immuno-suppression,anti-allergicandantiinflammatory; therapeutic users; toxicity; contraindications; esters and salts of corticoids andtheir formulation suitability. A detailed study of the following classes with additionalinformationindicated.

(i) **Systemicglucocorticoids**: list of compounds and their derivatives; classification;interconversion of cortisone and hydrocortisone; prednisone and prednisolone; rationale behinddevelopment of so many glucocorticoids; effect of substituent groups on glucocorticoid /mineralocorticoidactivity;relative potencies;derivatives;formulation.

(ii) **Topical glucocorticoids;** systemic absorption; determining relative potency; classification;compoundsused;formulations;the21-chlorocorticoids;non-fluorinatedcompounds;theirrelationtoknowncorticoids;metabolismofprednicarbate anditslowsystemic side effects.

(iii) **Inhaled and intranasalglucocorticoids**:pharmacokineticsproperties/qualitiesdesirableforthese compounds; modification of pharmacokinetics through modification of structures and itsconsequences;specialqualitiesofthenewinhaledandintranasalglucocorticoids;characteristicsof inhaledglucocorticoidsusedinasthma and allergic rhinitis; namesofinhalers.

(iv) **Ophthalmicglucocorticoids**:Differenceinstructurebetweenophthalmicandother glucocorticoids.

(d) **Steroidalantifertilityagents:**History;estrogens;pregnaneprogestins;androstanes;importance s of ethisterone; development of 19-norandrostanes; structures; mechanism of action;role of estrogens; regimens; toxicity; metabolism of desogestrel and norgestimate; androgenicactivity; uses of medroxyprogesterone, norethindrone, magestrol acetate. Progestinantagonists.Steroidreceptors-newinsights.

(e) **Anabolicsteroids:**Rationalefordevelopment;19-norandrogens (19-nortestosteronederivatives);androstanes;oxasteroids;heterocyclicringfusedcompounds;experimentalcompounds;structures;therapeutic uses;sideeffects.

(f) **Steroidsinthetreatmentofcancers:**Estrogens;antiestrogens;aromataseinhibitors;progestins; progestin antagonists; androgens and anabolic steroids; antiandrogens; 5α-reductaseinhibitors;gonadotropininhibitors;glucocorticoids.

UNITV **10Hours**

Cephalosporins:

Historicalbackground;classification;structures;numberingtheringsystem;nomenclature;degradation; spectrum of activity; SAR; β-lactamase resistance; antipseudomonalcephalosporins;mechanismofaction;uses;toxicity;developmentofnew cephalosporins-recentadvances;prodrugsincephalosporins;penicillinsVscephalosporins-acomparative account of the structural features and biological activity; β-lactamase inhibitors;mechanismofβ-lactamaseinhibition;monobactams.

REFERENCE

1. TextbookofWilsonand GisvoldsorganicmedicinalandpharmaceuticalbyCharlesOwensWilon,12thedition,2010,publisher:LippincottWilliams&Wilkins.
2. Foyesprinciplesofmedicinalchemistry,7theditionbyLemke, ThomasL,8thedition,2019,LippincottWilliams&Wilkins.
3. Burgersmedicinalchemistry,drugdiscoveryanddevelopmentbyDonaldJ.Abraham, 8volumes,8th edition,2021.
4. OrganicChemistryOfNaturalProducts,volumes1&2,GurdeepChatwal,Himalayapublishinghouse.
5. Organicchemistryofnaturalproducts,volumes1&2,O.P.Agarwal.
6. Organicchemistry,volume2,I.L.Finar,5thedition,1975.
7. Elementsofbiotechnology,P.K.Gupta, Rastogipublishers.
8. Pharmaceuticalbiotechnology,S.P.Vyas&V.K.Dikshit,CBSPublishers.

CHEMISTRYOFNATURALPRODUCTS(MPC105P)

1. Isolationandpurificationofsomeofthefollowingnaturalproducts.
    a. Piperinefromblackpepper
    b. StrychnineandBrucinefromStrychnosnuxvomicaseeds
    c. CaffeinefromTeaPowder
    d. CurcuminfromTurmeric
    e. BixinfromBixaorellanaseeds
    f. DiosgeninfromDiascoriatubers
    g. SennosidesfromSennaleaves
    h. EmbelinfromEmblicaribesfruits

2. The use ofcolumn, flash and cuumliquidchrmatographiesforisolatingsomeoftheabovementionedphytoconstituents

3.

1. IdentificationofalkaloidsinmixturebyTLC.
2. PreparativeTLCforseparationandisolation of alkaloids
3. Identificationofphytoconstituentslikealkaloids,steroids, flavanoidsetcinplantextractsbyTLC.
4. Separationofsugars/aminoacidsbypaperchromatography.
5. SeparationofcompoundsbyHPLC
6. Analysisofrecordedspectraofsomesimpleorganiccompounds.
7. Teststodetectalkaloids,steroids,flavanoidsandtheirglycosides.

BooksRecommended:

1. Naturalproducts,alaboratoryguide–RephaelIkan.
2. Laboratoryhandbookforthefractionofnaturalextracts– PeterJ.Houghton&AmalaRaman.
3. AnAtlasofTLC–H.Wagner.

ADVANCEDMEDICINALCHEMISTRY–I(MPC106P)

1. Synthesis,purificationandidentificationsomeofthe

followingdrugs.a)Sulfanilmideb)Uracilc)Phenytoind)Ibuprofene)para-

Aminosalicylicacid(PAS)f)Paracetamol
g)Atenolol(h)proranolol.i)Benzocaine

2. Screeningforthefollowingactivities
- CNS–RotarodexperimentCatatoniatesting
- Experimentsonisolatedtissues–Testingforanti-histaminicandanti-cholinergicactivities.
- Localanestheticactivity.

3. Spectralanalysis:
- Spectratoberecordedforsomecompoundsandanalyzed.
- Analysisofpre-recordedspectra.

BooksRecommended:
PracticalOrganicChemistry–Vogel.

Organicchemistryofsyntheticdrugs–Lednicer.

SEMESTER-II

Spectroscopic Identification of Organic Compounds

(MPC201T)THEORY **60Hours**

Objective:

StudentsofM.Pharm,Pharmaceutical/MedicinalChemistrybranchcarry outresearchinIIIandIVsemesters.Theysynthesizeorganiccompoundsorisolatenaturalcompoundsan dscreenthemforbiological activity.Theyhavetocharacterizethecompounds.Thishelpsinidentifyingorganiccompoundsbyspectr oscopicmeans.Theaimofthiscourseistotrainthestudentinthespectroscopic techniques so that he will be able to interpret different spectra andelucidate/confirmthestructureofcompoundshehasisolated/synthesized.Therefor e,theemphasiswhileteachingthesubjectshouldbeontheapplicationsofthetechniques.Adetailedstudy ofapplicationsofthefollowingspectroscopictechniquesinthedeterminationofstructureofthefollowin gclassesofcompoundswiththehelpofsimpleexamplesistobetaught.(i)Alkanesandcycloalkanes(ii)Al kenesandalkynes(iii)Aldehydesandketones(iv)Alcoholsandphenols(v)Carboxylicacidsandderivati ves(vi)Aromaticcompoundsandarenes(vii)Amines(viii)Alkylandarylhalides(ix)Simpleheterocycli ccompounds.The followingtechniquestobetaught:

UnitI: **10Hours**

a. **UV Spectroscopy**: Woodward-Fieser rules; Applications of UV-Visible spectroscopy instructuralelucidation;Studyofketo-enoltautomerism;Solvingproblems.**(3-4Hours)**
b. **IR spectroscopy:** Theory and instrumentation in brief. Molecular vibrations; Factorsinfluencing vibrational frequencies; Sampling techniques; Finger print region; Study ofKeto-enol tautomerism; intra & inter-molecular hydrogen bonding; Studying progress inChemical reactions; geometric and rational isomerism; Conformational analysis; spectralfeaturesofClassesofcompoundsindicatedabove.Solving problems.**(6-7 Hours)**

UnitII:Massspectrometry: **12Hours**

Theoryandinstrumentation.Ionizationtechniques-EI,CI,ESI,FAB,MALDIetc.Highresolution MS; Molecularions; importantfeatures of molecular ion peak; Determination ofmolecular formula; Mc Lafferty rearrangement; Metastable ions or peaks; Isotope peaks, Thenitrogen rule; general fragmentation modes; Fragmentation in the classes of compoundsindicatedabove.Problems andtheirsolution.

UnitIII:^{1}HNMR **10Hours**

Theoryandinstrumentationinbrief.Solvents;Numberofsignalschemicalequivalence,stereochemical equivalence in predicting the number of signals. intensity of signals; Chemicalshift; factors influencing chemical shift; Spin-Spin Coupling; Coupling Constants;long- rangecoupling; Shielding and deshielding; Magnetic anisotropy; Protons on oxygen and nitrogen;Protonexchange;NMRspectraoftheclassesofcompoundsindicatedabove.Problemsandthei rsolution.

UnitIV:^{13}CNMR,DEPTand2DNMR **18Hours**

a. Differences between^{1}H and ^{13}C NMR; Chemical shifts and scale; proton-coupled andproton-decoupled^{13}Cspectra;Off-resonancedecoupling;Solvents;Couplingofcarbontodeuterium,fluorineandphosphorus;Spectra of theclassesof compoundsindicatedabove.Problemsandtheirsolution.

b. AnaccountofDEPT. InterpretationofDEPTspectra.

c. Abriefaccountofthefollowing2DNMRtechniques withemphasisontheinterpretation of thespectraandtheiruse.

(a) COSY(b)HETCOR(c)HSQC,HMBC(d)HMBC

Problems and their solution: Students are to be provided with the spectra of simple compoundsand taught their interpretation. How they help in confirming the structural features, the^{1}H and ^{13}CNMRassignments ofcompoundsis tobetaught.

UNITV:Problemsandtheirsolution. **10Hours**

Determination of structures using a combination ofspectra/spectral data. Here the emphasis isonsolvingproblemsthroughinterpretationofdifferentspectraordatalikeUV,IR,Mass,^{1}Hand ^{13} C NMR including 2D-NMR spectra. Simple problems to be worked from books like Pavia,Silverstein, Field etc., mentioned under the "Books recommended" sections, apart from otherbooks.

BooksRecommended:

1. OrganicChemistry-MorrisonandBoyd-alongwiththestudyguide.
2. Spectroscopy-Pavia,Lampman,Kriz,Vyvyan-Publisher:Book/cole,Cengagelearning.
3. Spectroscopicmethodsofidentificationoforganiccompounds-Silverstein,Webster,Kiemle, Bryce.8th edition-Wiley.
4. StructureelucidationbymodernNMR,aworkbook-Duddeck,DetrichandToth.
5. Elementaryorganicspectroscopy-Y.R.Sharma.Publisher:S.Chand.
6. Spectroscopyoforganiccompounds-P.S.Kalsi.Publisher:NewAgeInternational Publisher.
7. Organicstructuresfromspectra-L.D.Field,H.L.Li,A.M.Magill-6thedition-Wiley.
8. Organicstructuresfrom2DNMRspectra-L.D.Field,H.L.Li,A.M.Magill-Published2015-Wiley.
9. Websites

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ADVANCEDORGANICCHEMISTRY–II(MPC202T)

THEORY **60Hours**

Objective:

Theaimofthecourseistoimpartknowledgetothestudentof:

- retrosynthesis
- chiralsynthesis
- greenchemistry
- peptidechemistry
- catalysis

UnitI: **12Hours**

Synthonapproachandretrosynthesisapplications

i. Basicprinciples,terminologiesandadvantagesofretrosynthesis;guidelinesfordissectionof molecules.

Functionalgroupinterconvertionandaddition(FGIandFGA),chemioselectivity,regioselectivity.

ii. C-Xdisconnections;C-Cdisconnections–alcoholsandcarbonylcompounds;1,2-, 1,3-,1,4-, 1,5-,1,6-difunctionalizedcompounds

iii. Strategiesforsynthesisofthree,four,fiveandsix-memberedring.

UnitII: **12Hours**

Stereochemistryandchiralsynthesis

a.Basicconceptsinstereochemistry–opticalactivity,specificrotation,racematesandresolution ofracemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudoasymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Znotation.

b. Chiral drug synthesis: Introduction to chiral drugs; importance of stereochemistry in drugaction; concepts of eutomer; distomer and eudesmic ratio, stereospecific and stereoselectivesynthesis;synthesisofchiraldrugslike Ibuprofen,Propranolol,Ramipril,Levofloxacin.

UnitIII **12Hours**

a. Green chemistry: Introduction, Green reagents; ionic solvents; phase transfer catalysis ingreensynthesis;applicationofphasetransfercatalystsingreensynthesisofheterocycliccompounds; Williamson'ssynthesis,Wittingreactions.

b. Microwaveassistedreactions:Meritanddemeritsofitsuse,increasedreactionrates,mechanism,su perheatingeffectsofmicrowave,effectsofsolventsinmicrowaveassistedsynthesis, microwave technology in process optimization, its applications in various organicreactionsandheterocycles synthesis

c. Microwaveassistedsynthesis: Introduction;microwavereactionsinwater(Hofmannelimination, hydrolysisandoxidation);microwavereactionsin organicsolvents; solidstatereactions;advantagesofmicrowavetechnique.

UnitIV **12Hours**

a. Chemistryofpeptides:
Definition,C-terminalandN-terminalconcept,endgroupanalysis,Abriefaccountonpharmaceuticalimportanceofpeptides andproteins.
b. Couplingreactionsinpeptidesynthesis
c. Principlesofsolidphasepeptidesynthesis,t-BOCandFMOCprotocols,varioussolidsupports and linkers: Activation procedures, peptide bond formation, deprotection and cleavagefrom resin, low and high HF cleavage protocols, formation of free peptides and peptide amides,purificationandcase studies,site-specific chemicalmodificationsofpeptides
d. Segment and sequentialstrategies for solution phase peptide synthesis with any two casestudies

UnitV **12Hours**
Catalysis:
Typesofcatalysis,heterogeneousandhomogenouscatalysis,advantagesanddisadvantages
a. Heterogeneouscatalysis–
Preparation,characterization,kinetics,supportedcatalysts,catalystdeactivation andregeneration,someexamples of heterogeneous catalysisusedinsynthesis ofdrugs.
b. Homogenouscatalysis,hydrogenation,hydroformylation,hydrocyanation,Wilkinsoncatalysts, chiralligandsandchiralinduction,Ziegler-Nattacatalysts,someexamplesofhomogenouscatalysis usedinsynthesis ofdrugs
c. Phasetransfercatalysis-theoryandapplications

REFERENCES

1. "AdvancedOrganicchemistry,Reaction,mechanismsandstructure",JMarch,JohnWileyands ons,NewYork.
2. "Mechanismandstructureinorganicchemistry",ESGould,HoldRinchartand Winston,NewYork.
3. "OrganicChemistry"Clayden,Greeves,WarrenandWoihers.,OxfordUniversityPress 2001.
4. "OrganicChemistry"VollandII.I.L.Finar.ELBS,Sixthed.,1995.
5. Carey,Organicchemistry,5thedition(VivaBooksPvt.Ltd.)
6. Organicsynthesis-thedisconnectionapproach,S.Warren,WilyIndia
7. Principlesoforganicsynthesis,ROCNormanandJMCoxan,Nelsonthorns
8. Organicsynthesis-SpecialtechniquesVKAhluwaliaandRAggarwal,NarosaPublishers.
9. OrganicreactionmechanismsIVedtn,VKAhluwaliaandRKParashar,NarosaPublishers.
10. TheoryandpracticeofGreenChemistry-PaulTAnastasandJohnC.Warner
11. NewtrendsinGreenChemistry-V.K.AhulwaliaandM.Kidwai
12. ChiroTechnology-RogerA.Sheldon

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COMPUTERAIDEDDRUGDESIGN(MPC203T)

THEORY **60Hrs**

Scope:

Thesubjectisdesignedtoimpartknowledgeonthecurrentstateofthearttechniquesinvolvedincomputer assisteddrugdesign.

Objectives:

Atcompletionofthiscourseitisexpectedthatstudentswillbeabletounderstand

- RoleofCADDindrugdiscovery
- DifferentCADDtechniquesandtheirapplications
- Variousstrategiestodesignanddevelopnewdruglikemolecules.
- Workingwithmolecularmodelingsoftwarestodesignnewdrug molecules
- Theinsilicovirtualscreeningprotocols
- Analyzeeffectivityofnew moleculesfrommedicinalchemistryperspective
- Correlatebiologicalresponsesofmoleculeswithdifferentattributes

Unit1.IntroductiontoComputerAidedDrugDesign(CADD) **12Hrs**

History,differenttechniquesandapplications.

Quantitative Structure Activity Relationships: Basics, History and development of QSAR:Physicochemicalparameters:Hydrophobicity(Thepartitioncoefficient(*P*),Thesubstituenthydrophobicityconstant(π),*P*versusπ);Electroniceffects(TheHammettsubstituentconstant(sigmaσx),andstericeffects(TaftstericandMRparameters).Methodstocalculatephysicochemicalparameters,withexamplessuchascalculationoflogPofchlorobenzene,benzamideand*m*-chlorobenzamide:HammettequationExperimentalandtheoreticalapproachesforthe determination ofthese physicochemical parameters explanation for steric and electronic factors and Craig plot andTopliss scheme. Quantitative Structure Activity Relationships(QSAR): ApplicationsHanschanalysis,FreeWilsonanalysisandrelationshipbetweenthem,Advantagesanddisadvantages;Deriving2D-QSARequations. 3D-QSARapproaches and contourmapanalysis. StatisticalmethodsusedinQSARanalysisandimportanceofstatisticalparameters.

Unit2:PharmacophoreMappingandVirtualScreening **12Hrs**

Conceptofpharmacophore,pharmacophore mapping,identificationofPharmacophore featuresandPharmacophoremodeling;Conformationalsearchusedinpharmacophoremapping. InSilicoDrugDesignandVirtualScreeningTechniques:SimilaritybasedmethodsandPharmacophorebasedscreening,structurebasedIn-silicovirtual screeningprotocols.Differentchemicalanddrug databases used invirtualscreening.

Unit3:MolecularModelingandDocking **12Hrs**

a) MolecularandQuantumMechanicsindrugdesign.BriefintroductiontoDFT(DenistyFunctional Theory)

b) EnergyMinimizationMethods:comparisonbetweenglobalminimumconformationandbioactive conformation

c) Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Different types of Scoring functions. Agents acting on enzymes such as DHFR,HMG-CoAreductaseand HIV protease, cholineesterase(AchE&BChE)

Unit4:MolecularPropertiesandDrugDesign **12Hrs**

a) PredictionandanalysisofADMET(Absorption,Distribution,Metabolism,Excretionand Toxicity)properties of new moleculesanditsimportanceindrugdesign.

b) Denovodrug design:Receptor/enzyme-interactionanditsanalysis,Receptor/enzymecavitysizeprediction,predictingthefunctionalcomponents ofcavities,Fragmentbaseddrugdesign.

c) Homologymodelingandgenerationof3D-structureofprotein. methodsandmathematicalexpressions,Proteinstructurevalidation, activesiteprediction

Unit5:Moleculardynamicsimulation(MDS)studies **12 Hrs**Introduction to MDS and software tools employed. Different file formats in GROMACS.Detailedprocess ofprotein inwater and protein-ligand complex inwater MDS. Analysis of MDStrajectories: RMSD(Root Mean Square Deviation),RMSF(Root Mean Square SquareFluctuation),Radiusof Gyrationandhydrogenbondanalysis.BriefmathematicalconceptofMM-PBSA(MolecularMechanics-Poisson-BoltzmannSurfaceArea)

REFERENCES

1. Computationalandstructuralapproachestodrugdiscovery,RobertMStroudandJanet.FMoore, RCSPublishers.
2. IntroductiontoQuantitativeDrugDesignbyY.C.Martin,CRCPress,Taylor&Francisgroup..
3. DrugDesignbyAriensVolume1to10,AcademicPress,1975,ElsevierPublishers.
4. PrinciplesofDrugDesignbySmithandWilliams,CRCPress,Taylor&Francis.
5. TheOrganicChemistryoftheDrugDesignandDrugactionbyRichardB.Silverman,Elsevier Publishers.
6. MedicinalChemistrybyBurger,WileyPublishingCo.
7. Justin A. Lemkul. FromProteins to Perturbed Hamiltonians: A Suite of Tutorials for the GROMACS-2018 Molecular. Simulation Package [Article v1.0]. Living J. Comp. Mol. Sci. 2019, 1(1), 5068.https://doi.org/10.33011/livecoms.1.1.5068(MDS)8.https://doi.org/10.3390/pr9010071OutiM.H.S alo-Ahen, Ida Alanko, et al., Molecular Dynamics Simulations in Drug Discovery and PharmaceuticalDevelopment.Development.Processes2021,9,71.https://doi.org/10.3390/pr9010071
9. GonçaloC.Justino1,2|CatarinaP.Nascimento2 |MartaC.Justino2,3.Moleculardynamicssimulationsandanalysisforbioinformaticsundergradua testudents. BiochemMolBiolEduc.2021;49:570–582.DOI:10.1002/bmb.21512
10. ComputationalMedicinalChemistryfor DrugDiscovery. EditedByPatrickBultinck, HansDeWinterWilfriedLangenaeker,JanP.Tollenaere
11. ErchengWang,HuiyongSun,JunmeiWang,ZheWang,HuiLiu,JohnZ.H.Zhang,andTingjun Hou.End-Point Binding Free Energy Calculation with MM/PBSA and MM/GBSA: Strategies andApplications in Drug Design Chemical Reviews 2019 119 (16), 9478-9508. DOI:10.1021/acs.chemrev.9b00055
12. Tingjun Hou, Junmei Wang, Youyong Li, and Wei Wang. Assessing the Performance of theMM/PBSAandMM/GBSAMethods.
1.TheAccuracyofBindingFreeEnergyCalculationsBasedonMolecular Dynamics Simulations. JournalofChemicalInformationandModeling2011 51 (1),69-82.DOI:10.1021/ci100275a
13. SamuelGenheden& UlfRyde(2015)TheMM/PBSAandMM/GBSAmethods to estimateligand-binding affinities, Expert Opinion on Drug Discovery, 10:5, 449-461, DOI:10.1517/17460441.2015.1032936

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ADVANCEDMEDICINALCHEMISTRY-II(MPC204T)

THEORY **60Hours**

Scope

Thesubjectisdesignedtoimpart knowledgeaboutrecentadvancesinthefieldofmedicinalchemistryat themolecularlevelincludingdifferenttechniquesfortherationaldrugdesign.**Objective:**

Theobjectiveofthecourseistoimpartanin-depthknowledgeofsyntheticdrugsbelongingtodifferentclasses,theirorigin,mechanismofaction,SAR,use andtoxicity.

UnitI: **12Hours**

Psychopharmacologicalagents: Biochemical basis of mentaldisorders;abnormalprotein factors;endogenous amines and related substances; faulty energy metabolism; genetic disorders andnutritional disorders; phenothiazines – chemistry; synthesis. Screening methods;pharmacologicalactions;SAR;mechanismofaction;uses;toxicity;ringanaloguesofphenothiazines;fluorobutyrophenones;Developmentofatypicalantipsychotics.ofChlorpromazine,Prochlorperazine,Fluphenazine,Haloperidol.

UnitII: **12Hours**

AnxiolyticsSedativesAndHypnotics:Screeningmethods;Benzodiazepinesandrelatedcompounds; barbiturates; other classes; mechanism of acition, SAR; uses and toxicity SynthesisofChlordiazepoxide,Diazepam,Alprazolam,Phenobarbital,Meprobamate.

UnitIII: **12Hours**

Antidepressants: MAOinhibitors; tricylic antidepressants; SAR; mechanism of action; uses;toxicityotherclasseslike:selectiveserotoninreuptakeinhibitors,selective5-HTandNEreuptake inhibitors;selectiveserotoninergicreuptake inhibitorsand5-HT2Aantagonists;5-HT1Aagonistsandpartialagonistsandα2-antagonists.SyntheisofTranycypromine,Amitriptyline,Fluoxetine,Buspirone.

UnitIV: **12Hours**

Antiepileptics&CNSstimulants:

a. Antiepileptics:Screeningmethods;classification ofepilepsies;symptoms;drugsused;classification; structural feactuers common to drugs; SAR; mechanism of action; toxicity anduses;synthesis ofDiphenylhydantion,Carbamazepine,SodiumValproate.

b.CNSstimulants:anaccountofthedrugswithCNSstimulantactivity;structuresanduses.

UnitV: **12Hours**

RationalDesignofEnzymeInhibitors

Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzymeinhibitors in basic research, rational design of non-covalently and covalently binding enzymeinhibitors.

BooksRecommended:

1. WilsonandGisvold'stextbookofpharmaceuticalorganicmedicinalchemistry.
2. Foye'sprinciplesofmedicinalchemistry.
3. Burger'stextbookofmedicinalchemistry
4. Organicchemistryofsyntheticdrugs–Lednicer.
5. Screeningmethodsinpharmacology–RobertA.Turner.
6. DrugEvaluation–Vogel.
7. EvaluationofDrugActivities--LawrenceandBachrach.
8. MethodsinPharmacology–Swarbrick.
9. MedicinalChemistry-SurendranathPandeya,VolumeIandVolumeII
10. MedicinalChemistry-Ashutoshkar,NewAgeInternationalPublications
11. Pharmacopoeias

ADVANCEDORGANICCHEMISTRY–I(MPC205P)

Someofthefollowingexperimentstobetaught.

1. BasicTechniques:

a) Calibrationofthermometerandfindingmeltingpoint,mixedmeltingpointandboilingpoint.
b) Purificationanddryingoforganicsolvents
c) Crystallization
d) Distillation,FractionalDistillation,Distillationunderreducedpressure

2. Separationandidentificationoforganiccompoundsfrombinarymixtures:

Solid-solid,solid-liquidandliquid-liquid–atleastonemixtureofeachcategorytobedone.

3. Synthesisofsomeofthefollowingheterocycliccompounds:

a)Quinolineb)benzimidazole/derivativec)flavone/chromoned)indole/derivativee)phenothiazinef) oxazole/oxazolone g)benzoxazole h)3,5 dimethylisoxazole

4. Someofthefollowingreactions:

1. Beckmann rearrangement 2) Fries rearrangement 3) Acetylation, methylation 4) Metal/acidreductions 5) Oppenauer oxidation 6) Friedel-Craafts alkylation & Acylation 7) Nitration usingdifferentreagents

BooksRecommended:

PracticalOrganicChemistry–Vogel.

ADVNCEDMEDICINALCHEMISTRY(MPC206P)

1. Synthesis,purificationandidentificationofsomeofthefollowingdrugs;
    a) Dapsone
    b) Benzocaine
    c) Hydralazine
    d) Imipramine
    e) Sufadiazine

2. Synthesisusingmicrowaveoven:oneexperimenttobeconducted
3. Screeningforthefollowingactivities:
    a) Analgesicactivity
    b) Antiinflammatoryactivity
    c) Acutetoxicitystudies
    d) Antibacterialandantifungalactivity
    e) Freeradicalscavengingandanti-oxidantactivities

4. SpectralanalysisSpectratoberecordedforsomecomp
oundsandanalyzed.Analysis ofpre-recordedspectra
2.Impurityprofilingforoneortwosa

BooksRecommended:

1. PracticalOrganicChemistry–Vogel.
2. Organicchemistryofsyntheticdrugs–Lednicer.

PHARMACEUTICALANALYSIS

.MODERNPHARMACEUTICALANALYTICALTECHNIQUES(MPA101T)

THEORY **10 Hours**

Scope: The appreciable knowledge will be gained by the students in the Modern Analytical Techniques and can apply the theories in the Analysis of various bulk drugs and their formulations. The students will also be in a position to apply their knowledge in developing the new methods for the determination and validate the procedures.

Objectives: The course is designed to impart the knowledge in different analytical techniques like UV-Visible, IR, GC, HPLC etc so that it can be used in the analysis of bulk drugs and formulations.

UNIT I **12Hours**

Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation

A. Column Chromatography: Adsorption and partition, materials used for separation, solvent system, procedure and method of detection. Theory, principles involved in separation, apparatus, column materials, number of theoretical plates, elution, method of detection. Modifications like VLC, Flash, MPLC, their advantage over open column CC.

B. Paper Chromatography: Theory, different techniques employed, filter papers used, qualitative and quantitative detection

UNIT II **12Hours**

A. Thin Layer Chromatography: Theory, principles of separation, apparatus, coating materials, spotting, solvent systems, detection, Uses of TLC: Finding the number of compounds; the class of compounds; Testing for purity/ detection of impurities; identifying compounds-Co-TLC, Mixed TLC; isolating compounds in a pure form-preparative TLC; Two dimensional TLC.

B. HPTLC: Theory and principle, instrumentation, elution techniques and pharmaceutical applications

C. A comparative study; how is HPTLC is different from TLC, apparatus; Coating materials-particle size; detection; uses.

UNIT II **12Hours**

a. Gas Chromatography: Introduction, fundamentals, instrumentation, columns: preparation and operation, detection; derivatization.

b. HPLC and UPLC: Principles and instrumentation, solvents and columns used, Operational modes, detection and applications.

UNIT III **12Hours**

A. Electrophoresis:Principle,Instrumentation,Workingconditions,factors affectingseparation and applications ofthefollowing:a) Paperelectrophoresisb)Gelelectrophoresisc)Capillary electrophoresis d) Zone electrophores e) Moving boundaryelectrophoresis f)Isoelectricfocus

B.X-rayCrystallography: Production of X rays, Different X raymethods, Bragg's law, Rotating crystal technique, X ray powdertechnique,Typesof crystalsandapplicationsofX-raydiffraction.

UNIT IV **12Hours**

A.UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect; Quantitative estimation of Riboflavin, Paracetamol, Diclofenac, Metronidazole,Aspirin..

B.IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier – Transform IR Spectrometer, Factors affecting vibrational frequencies, Quantitative estimation of APIs using IR spectroscopy.

UNIT V **12Hours**

A. Spectro flourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

B. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein,Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1996. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

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ADVANCED PHARMACEUTICAL ANALYSIS-I (MPA 102T)

THEORY **60 Hrs**

Scope: The principles and procedures for the determination of various pharmaceutical bulk drugs and their formulations belonging to differentcategories are discussed in detail. The applications of the important reagents like MBTH, FC, PDAB, 2, 3, 5 - triPhenyltetrazolium salt , . 2,6 di -ChloroquinoneChlorimide ,N - (1-naphthyl) ethylenediaminedihydrochloride (B.M. Reagent), Carr price reagent etc. in the determination of the pharmaceuticals are also discussed.

Objective: The quantitative determination of various organic compounds is clearly understood. The spectral analysis, dissolution parameters and microbial assays are also learned.

UNIT I **12Hours**

a. Impurityandstabilitystudies:
Definition, classification of impurities in drug Substance or ActivePharmaceutical Ingredients and quantification of impurities as perICHguidelines

b.Impuritiesinnewdrugproducts:
Rationale for the reporting and control of degradation products,reportingdegradationproductscontentofbatches,listingofdegradation productsin specifications, qualificationof degradationproducts

c. Impuritiesinresidualsolvents:
General principles,classification of residualsolvents, Analyticalprocedures,limits of residualsolvents, reporting levels of residualsolvents

UNIT II **12Hours**

A. Principles and procedures involved in the determination of the official compounds in IP with the following analytical techniques

A. Non-aqueous
B. Oxidation-reduction
C. Complexometric
D. Diazotization methods
E. Neutralization
F. Acid – Base

B.A detailed study of the principles and procedures involved in the quantitative determination of the following organic functional groups

A. Amines
B. Esters
C. Carbonyl compounds
D. Hydroxy and carboxyl
E. Amino Acids

UNIT III **12Hours**

Principles and procedures involved in using the following reagents in the determination of pharmaceutical dosage forms official in IP

a. MBTH (3-methyl-2-benzothiazolone hydrazone)

b. F.C. Reagent (Folin-Ciocalteu)
c. PDAB (para-Dimethyl Amino Benzaldehyde)
d. 2, 3, 5 - triPhenyltetrazolium salt
e. 2,6 di -ChloroquinoneChlorimide
f. N - (1-naphthyl) ethylenediaminedihydrochloride (B.M. Reagent)
g. Carr – Price Reagent
h. 2,4 – DNP

UNIT – IV **12Hours**

Elemental impurities: Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis.

UNIT-V **12Hours**

a.Biological tests and assays of the following:

a. Adsorbed Tetanus vaccine
b. Adsorbed Diphtheria vaccine
c. Human anti haemophilic vaccine
d. Rabies vaccine
e. Tetanus Anti toxin
f. Tetanus Anti serum
g. Oxytocin
h.Heparin sodium IP
i. Antivenom.

b. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)
c. Microbiological assays and Biological tests: Antimicrobial effectiveness testing, microbial limit tests, sterility test. Antibiotics-microbial assays, bacterial endotoxins test.

REFERENCES:

1. Pharmaceutical Chemistry by Becket and Stanlake
2. Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
3. Instrumental Methods of Chemical Analysis By B.K. Sharma
4. A Text Book of Pharmaceutical Analysis by Kennenth A. Conners
5. Organic spectroscopy by Y.R Sharma Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
6. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
7. Remington's Pharmaceutical Sciences by Alfonso and Gennaro
8.Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D. Sethi
9.Indian Pharmacopoeia 2010.
10.Journals (Indian Drugs, IJPS etc

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PHARMACEUTICAL VALIDATION (MPA 103T)

THEORY **60Hours**

Scope: The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Objective: Upon completion of the subject student shall be able to

Explain the aspect of validation
Carryout validation of manufacturing processes
Apply the knowledge of validation to instruments and equipments

UNIT I **12Hours**

Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.
Validation of Manufacturing Equipment, Qualification of Analytical Instruments and Laboratory equipments.

UNIT II **12Hours**

Validation of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC.
Validation of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT III **12Hours**

Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.

Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment. Cleaning of Facilities. Cleaning in place (CIP).

UNIT IV **12Hours**

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP. Validate the manufacturing facilities

UNIT V **12Hours**

a. General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in Pharmaceutical industry; Global ramification and financial implications.

b. Patent: Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope.

c. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.

REFERENCES:

1. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Pharmaceutical Facilities: Design, Layouts and Validation, Potdar,Pharmamed Press
6. Michael Levin, Pharmaceutical Process Scale-Upl, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
8. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J.Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam

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FOODANALYSIS (MPA104T)

60Hrs

Scope

This courseis designedto impart knowledgeon analysis of food constituentsand finishedfood products.The courseincludesapplicationof instrumentalanalysisinthedeterminationofpesticidesinvarietyoffoodproducts.

Objectives

Atcompletionofthiscoursestudentshallbe able tounderstand variousanalyticaltechniquesinthedeterminationof

- Foodconstituents
- Foodadditives
- Finishedfoodproducts
- Pesticidesinfood
- And alsostudentshallhave theknowledgeon foodregulationsandlegislations

UNIT-I

12Hours

Carbohydrates:classificationandpropertiesoffood carbohydrates,Generalmethodsofanalysisoffoodcarbohydrates, Changesin food carbohydrates during processing,Digestion, absorptionand metabolism of carbohydrates, Dietaryfibre,Crudefibreandapplicationoffoodcarbohydrates

Proteins:Chemistryandclassificationofaminoacidsandproteins,Physico-Chemicalpropertiesofprotein and their structure, general methods of analysis of proteins and aminoacids,Digestion,absorptionandmetabolism of proteins

UNIT-II

12Hours

Lipids : Classification , general methods of analysis , refining of fats and oils; hydrogens of vegetables oils, determinations of adulteration in fats and oils, various methods used for measurements of spoilage of fats and fatty foods .

Vitamins: Classification of vitamins methods of analysis of vitamins, principle of microbial assay of vitamins of B –series

UNIT-III

12Hours

Food additives: Introduction, analysis of preservatives, antioxidants, artificial sweeteners, flavors, flavor, enhancers, stabilizers, thickening and jelling agents.

Pigments and synthetic dyes: Natural pigments , their occurrences and characteristics properties , permitted synthetics dyes , Non permitted synthetics dyes used by industries , Method of detection of natural , permitted and Non permitted dyes.

UNIT-IV

12Hours

General Analytical methodsfor milk, milk constituentsand milkproducts like ice cream,milk powder, butter, margarine, cheeseincluding adulterantsandcontaminantsofmilk Analysis of fermentation products like wine, spirits, beer and vinegar

UNIT-V

12Hours

Pesticide analysis: Effects of pest and insects on various food,useof pesticidesinagriculture, pesticidecycle,organophosphorusand organochlorine pesticides analysis,determinationof pesticide residues in grain,fruits, vegetables,milkandmilkproducts.
Legislationregulationsoffoodproductswithspecialemphasis onBIS,Agmark,FDAandUS-FDA.

REFERENCES

1. Thechemicalanalysisoffoods–DavidPearson,Seventhedition,ChurchillLivingstone,EdinburghLondon,1976
2. IntroductiontotheChemicalanalysisoffoods–S.Nielsen,Jones&Bartlettpublishers,BostonLondon,1994.

3. OfficialmetbodsofanalysisofAOACInternational,sixthedition,VolumeI &II,1997.
4. AnalysisofFoodconstituents–Multon,WileyVCH.
5. Dr.WilliamHorwitz,OfficialmethodsofanalysisofAOACInternational,18thedition,2005.

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MODERN PARMACEUTICAL ANALYTICAL TECHNIQUES LAB (MPA 105P)

LIST OF EXPERMINTS

1. Calibration of glassware
2. Calibration of pH meter
3. Identification of Amino acids by Paper Chromatography
4. Identification of Amino acids by Thin Layer Chromatography
5. Identification of Alkaloids by Thin Layer Chromatography
6. Calibration of UV- Visible spectrophotometer
7. Calibration of HPLC instrument
8. Determine the λ max of $KMNO_4$
9. Assay of Ibuprofen by using U.V spectrophotometer
10. Assay of Paracetamol by using U.V spectrophotometer
11. Assay of Metronidazole by using U.V spectrophotometer
12. Assay of Aspirin by using U.V spectrophotometer
13. Assay of Aceclofenac by using U.V spectrophotometer
14. Assay of Nimesulide by using U.V spectrophotometer
15. Calibration of Ondansetron by using U.V spectrophotometer
16. Assay of caffeine by using HPLC
17. Assay of Nimesulide by using HPLC
18. Determination of Viscosity of Different Polymeric Solution By Brook Field Viscometer
19. Effect of Concentration on Viscosity of Glycerin Solution By Brook Field Viscometer

ADVANCED PHARMACEUTICAL ANALYSIS-I LAB (MPA 106P)

LIST OF EXPERIMENTS:

1. Determination of Acid value
2. Determination of Fatty acid
3. Determination of Saponification value
4. Determination of Ester value
5. Determination of Peroxide value
6. Determination of Acetyl value
7. Determination of Iodine value
8. Determination of Hydroxyl value
9. Assay of ascorbic acid
10. Assay of Atropine sulphate
11. Assay of Ammonium chloride
12. Assay of Magnesium carbonate
13. Assay of Mohr's salt
14. Spectrophotometric determination of Nimesulide by colorimetry
15. Colorimetric estimation of Metronidazole by vanillin
16. Colorimetric estimation of Metronidazole by PDAB
17. Estimation of Creatinine in urine by alkaline pictrate (jaffe's method)
18. Assay of Aceclofenac by FC reagent
19. Determination of Quinine sulphate by fluorimetry
20. Determination of amount of amine salts by titration in aqueous solutions
21. Assay of Ascorbic acid by UV spectrophotometer
22. Assay of Riboflavin by UV spectrophotometer
23. Determination of sulphates by nephlometry
24. Potentiometric titration of strong acid and strong base
25. Potentiometric titration of weak acid and strong base
26. Conductometric titration of strong acid and strong base

SEMESTER-II **ADVANCED INSTRUMENTAL ANALYSIS (MPA 201T)**

THEORY **60 Hours**

Scope: This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are , X-ray crystallography, super critical chromatography and hyphenated techniques.

Objective: By the completion of topics the students will come out with the thorough knowledge of various spectral aspects of X-Ray, IR, SEM, ORD etc which help them in further projects works and also industrial opportunities.

Unit I: **10 Hours**

a. UV Spectroscopy: Woodward-Fieser rules; Applications of UV-Visible spectroscopy in structural elucidation; Study of keto-enol tautomerism; Solving problems. **(3-4 Hours)**

b. IR spectroscopy: Theory and instrumentation in brief. Molecular vibrations; Factors influencing vibrational frequencies; Sampling techniques; Finger print region; Study of Keto-enol tautomerism; intra & inter-molecular hydrogen bonding; Studying progress in Chemical reactions; geometric and rational isomerism; Conformational analysis; spectral features of Classes of compounds indicated above. Solving problems. **(6-7 Hours)**

Unit II: Mass spectrometry: **12 Hours**

Theory and instrumentation. Ionization techniques-EI, CI, ESI, FAB, MALDI etc. High resolution MS; Molecular ions; important features of molecular ion peak; Determination of molecular formula; Mc Lafferty rearrangement; Metastable ions or peaks; Isotope peaks, The nitrogen rule; general fragmentation modes; Fragmentation in the classes of compounds indicated above. Problems and their solution.

Unit III: ^{1}H NMR **10 Hours**

Theory and instrumentation in brief. Solvents; Number of signals chemical equivalence, stereochemical equivalence in predicting the number of signals. intensity of signals; Chemical shift; factors influencing chemical shift; Spin-Spin Coupling; Coupling Constants;long- range coupling; Shielding and deshielding; Magnetic anisotropy; Protons on oxygen and nitrogen; Proton exchange; NMR spectra of the classes of compounds indicated above. Problems and their solution.

UNIT IV **12 Hours**

a. Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.

b. Super critical fluid chromatography: Principles, instrumentation, pharmaceutical applications.

c. **Scanning electron microscope (SEM):** Principles, Instrumentation and applications. Optical Rotatory Dispersion (ORD), Circular Dichroism, Cotton effect, Octane rule and applications.

UNIT V **10Hours**

a. DSC: Principle, thermal transitions, instrumentation (Heat flux and power- compensation designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, Sources of errors) and their influence, advantages and disadvantages, pharmaceutical applications.

b. DTA: Principle, instrumentation, advantage and disadvantage, pharmaceutical application, derivative differential thermal analysis (DDTA).

c. TGA: Principle, instrumentation, factors affecting results, advantages and disadvantages, pharmaceutical application.

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REFERENCES:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
3. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
4. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
5. Organic Chemistry by I. L. Finar
6. Quantitative Analysis of Drugs by D. C. Garrett
7. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi

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MODERN BIO-ANALYTICAL TECHNIQUES (MPA 202T)

THEORY **60 Hrs**

Scope: This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

Objective: Upon completion of the course, the student shall be able to understand
Extraction of drugs from biological samples
Separation of drugs from biological samples using different techniques
Guidelines for BA/BE studies

UNIT I **12 Hours**

Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid -Liquid extraction and Solid phase extraction and other novel sample preparation approach.

UNIT II **12 Hours**

Biopharmaceutical Consideration: Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

UNIT III **12 Hours**

Bioanalysis and bioanalytical method validation:
a. Types of body fluids, requirement of analysis, matrix effects, non-biological analytical samples.
b. Bioanalytical method validation: USFDA and EMEA guidelines. Acceptance criteria in comparison to non-biological samples.

UNIT IV **12 Hours**
Cell culture techniques

a. Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures;isolation of cells, subculture, cryopreservation, characterization of cells and their applications.
b.Principles and applications of cell viability assays (MTT assays)
c. Principles and applications of flow cytometry.

UNIT V **12 Hours**
Drug Product Performance, In Vivo: Bioavailability and Bioequivalence:
Drug Product Performance, Purpose of Bioavailability Studies,Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

REFERENCES:

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition.CRC Press, New York. 1995.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, New York, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jersey, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines

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QUALITY CONTROL AND QUALITY ASSURANCE (MPA 203T)

THEORY **60 Hrs**

Scope: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objective: The study of this subject builds the confidence in the minds on the students to develop and formulate high quality pharmaceutical products.

Unit I **12 Hours**

Concept of quality assurance, total quality management, philosophy of GMP, cGMP and GLP, organization and functioning of accreditation bodies: ISO 9000, ISO 14000, NABL and OSHA 18000

Unit II **12 Hours**

a. Organization and personal, responsibilities, training hygiene

b. Premises: Location, design, plan layout, construction, maintenance and sanitations, environmental control, sterile area, control of contamination

c. Equipments: selection, purchase, specifications, maintenance, clean in place, sterilized in place - Raw – materials; purchase specifications, maintenance of stores, selection of vendors, controls and raw materials

Unit III **12 Hours**

Manufacture and controls on dosage forms

a. Manufacturing documents, master formula records, batch formula records, standard operating procedures, Quality audits of manufacturing processes and facilities

b. In process quality control on various dosage forms sterile, biological products and non-sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.

c. Guideline for Quality Assurance of Human Blood Products and large volume parenterals.

Unit-IV **12 Hours**

a. Packaging and labeling controls, line clearance and other packaging materials.

b. Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities – finished products release: quality review, quality audits and batch release document.

Unit V **12 Hours**

a. Distribution and Distribution records: Handling of returned goods recovered materials and reprocessing.

b. Complaints and recalls, evaluation of complaints recall procedures, related records and documents.

REFERENCES:

1. The International Pharmacopoeia Vol 1,2,3,4, 3rd edition: General methods of analysis quality specifications for Pharmaceutical substances, Excipients, dosage forms.
2. Quality Assurance of Pharmaceuticals. A compendium of guidelines and related material Vol.1 and Vol.2, WHO (1999)
3. GMP- Mehra
4. Pharmaceutical Process Validation – Berry and Nash
5. Basic test for Pharmaceutical substances-WHO(1988)
6. Basic test for Pharmaceutical substances-WHO(1991)
7. How to practice GMP's-P P SharmaVandanaPublications,Agra,1991.
8. The drugs and cosmetics Act-1940-Deshpande, NileshGandhi,4th edition,SusmitPublishers,2006.
9. QA Manual byD.H. Shah, 1st edition, Business Horizons, 2000.
10. SOP guidelines by DH Shah
11. Quality Assurance guide-OPP
12. Quality AssuranceGuide by organizationof PharmaceuticalProcedures ofIndia,3rd revisededition,VolumeI&II,Mumbai,1996.
13. GoodLaboratoryPracticeRegulations,2nd Edition,SandyWeinbergVol.69,MarcelDekkerSeries,1995.
14. QualityAssuranceofPharmaceuticals-AcompediumofGuidelinesand Relatedmaterials VolI&II,2nd edition,WHOPublications,1999.
15. TheInternationalPharmacopoeia–volI,II,III,IV&V-GeneralMethodsofAnalysisandQualityspecificationforPharmaceuticalSubstances,ExcepientsandDosageforms,3rd edition,WHO,Geneva,2005.
16. GoodlaboratoryPracticeRegulations–AllenF.Hirsch,Volume38,MarcelDekkerSeries,1989.
17. ICHguidelines
18. ISO9000andtotalqualitymanagement
19. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
20. SteinbornL.GMP/ISOQualityAuditManualforHealthcareManufacturers and TheirSuppliers, Sixth Edition, (Volume1 -With ChecklistsandSoftwarePackage).Taylor&Francis;2003.
21. SarkerDK.QualitySystemsandControlsforPharmaceuticals.JohnWiley &Sons;2008

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ADVANCED PHARMACEUTICAL ANALYSIS - II (MPA 204T)

Scope: The principles and procedures for the determination of various pharmaceutical bulk drugs and their formulations belonging to different categories are discussed in detail. The applications of the important reagents like GLC, GC-MS, HPLC, HPTLC, UV/Vis, LC-MS, MS-MS etc. in the determination of the pharmaceuticals are also discussed.

Objective: The qualitative and quantitative determination of various organic compounds is clearly understood. The chromatographic techniques, elemental analysis, evaluation of cosmetic products are also learned.

Unit I **12 Hours**

An advanced study of the principles and procedures and applications of instrumental methods in the development of medicines (GLC, GC-MS, HPLC, HPTLC, UV/Vis, LC-MS, MS-MS)

Unit II **12 Hours**

a. Elemental analysis such as determination of sodium, potassium, calcium, phosphorous, sulphur, chlorine, bromine and Iodine,
B. Optical rotator dispersion technique for the analysis of chiral compounds

Unit III **12 Hours**

An advanced study of the principles and procedures involved in the instrumental methods and applications of Flame Photometry, Fluorimetry, Nephelo - Turbidimetry and Refractrometry, Study of general principles and methods for the determination of Proteins, Carbohydrates, Fats, Crude fibre, Moisture and Nitrogen

Unit IV **12 Hours**

a. Evaluation of cosmetic products: Determination of Ash, volatile matter, heavy metals, fineness ofPowder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per
BIS.
b. Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau of Indian Standards.

Unit V **12 Hours**

a.Identification and quantitative determination of preservatives, Antioxidants, Colouring materials, Emulsifiers and Stabilizers in Pharmaceutical formulation
b.Methodology involved
Moisture content determination in dosage forms
Alcohol determination
Essential oil determination
Surfactant analysis

REFERENCES:

1. Remington's Pharmaceutical Sciences – Alfonso and Gennaro
2. Pharmaceutical Chemistry – Becket and Stanlake
3. Quantitative Analysis of Drugs in Pharmaceutical Formulations – P.D. Sethi

4. Pharmaceutical Analysis – Higuchi, Bechmman and Hassan
5. Theory and Practice of Industrial Pharmacy – Liebermann and Lachmann
6. Indian Pharmacopoeia – 1996
7. Instrumental Methods of Chemical Analysis – B.K. Sharma
8. A Text Book of Pharmaceutical – Kenneth A. Conner
9. Thechemicalanalysisoffoods–DavidPearson,Seventhedition,ChurchillLivingstone,EdinburghLondon,1976
10. IntroductiontotheChemicalanalysisoffoods–S.Nielsen,Jones&Bartlettpublishers,BostonLondon,1994.
11. OfficialmethodsofanalysisofAOACInternational,sixthedition,VolumeI &II,1997.
12. AnalysisofFoodconstituents–Multon,WileyVCH.
13. .Dr.WilliamHorwitz,OfficialmethodsofanalysisofAOACInternational,18thedition,2005.

ADVANCED INSTRUMENTAL ANALYSIS (MPA 205P)

1. Preparation and In-process quality control test for Immediate released tablets
2. System suitability parameters for HPLC
3. Analytical method development for given drug by using HPLC
4. Determination of linearity and range by using HPLC
5. Determination of accuracy and precision by using HPLC
6. Determination of specificity by using HPLC
7. Determination of robustness by using HPLC
8. Determination of ruggedness by using HPLC
9. Determination of Limit of Detection and Limit of Quantitation by using HPLC
10. Analytical method development for Ibuprofen by using U.V spectroscopy
11. Determination of linearity and range by using U.V spectroscopy
12. Determination of accuracy and precision by using U.V spectroscopy
13. Determination of specificity by using U.V spectroscopy
14. Determination of robustness by using U.V spectroscopy
15. Determination of ruggedness by using U.V spectroscopy
16. Determination of Limit of Detection and Limit of Quantitation by using U.V spectroscopy
17. Assay of ibuprofen by using U.V spectroscopy
18. Standard addition method in support of determination of accuracy of the method by using U.V spectroscopy
19. Stability testing of drug substances as per ICH
20. Short term stability studies at different pH
21. pH dependent saturation solubility testing of given API
22. Determination of drug release kinetics of given CR/ER/SR tablets by dissolution testing method
23. Optimization of solvent system for immiscible liquids by ternary phase diagram

ADVANCED PHARMACEUTICAL ANALYSIS-II PRACTICALS (MPA 206P)

1. Determination of the percentage of sodium chloride by Mohr's method
2. Determination of the percentage of sodium chloride by Volhard's method
3. Estimation of Sulphate ions by Nephelometry
4. Determination of Linearity and Range of an analytical method to determine the content of sulphate ions by Nephelometry
5. Determination of Accuracy and Precision of an analytical method to determine the content of sulphate ions by Nephelometry
6. Determination of LOD(Limit of Detection) and LOQ(Limit of Quantitation) of an analytical method to determine the content of sulphate ions by Nephelometry
7. Determination of amount of amines present in Hydroxylamine Hcl
8. Estimation of Sodium ions by Flame photometry
9. Determination of unknown concentration of Quinine sulphate Fluorometry
10. Determination of Quenching effect of Quinine sulphate by Potassium iodide solution in Fluorometry
11. Estimation of unknown concentration of Glycerin by Abbe's Refractometry
12. Estimation of unknown concentration of Tartaric acid by Polarimetry
13. Assay of Diclofenac sodium and Paracetamol by SEM(Simultaneous Equation Method) by using U.V spectrophotometer
14. Assay of Ibuprofen and Paracetamol by SEM (Simultaneous Equation Method) by using U.V spectrophotometer
15. Assay of Diclofenac sodium by using U.V spectrophotometer

SemesterIII

MRM301T-ResearchMethodology&Biostatistics

(Commontoallspecializations)

UNIT–I

General Research Methodology: Research, objective, requirements, practical difficulties, reviewofliterature,studydesign,typesofstudies,strategiestoeliminateerrors/bias,controls,randomization,crossoverdesign,placebo,blindingtechniques. **10Hrs**

UNIT–II

Biostatistics: Definition, application, sample size, importance ofsample size, factors influencingsamplesize,dropouts,statistical tests of significance,typeof significancetests,parametrictests(students"t"test,ANOVA,Correlationcoefficient,regression),non-parametrictests(wilcoxan rank tests, analysis of variance, correlation, chisquare test), null hypothesis, P values,degreeoffreedom,interpretationofP values. **10Hrs**

UNIT–III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence,doubleeffect,conflictsbetweenautonomyandbeneficence/non-maleficence,euthanasia,informedconsent,confidentiality,criticismsoforthodoxmedicalethics,importanceofcommunication,controlresolution,guidelines,ethicscommittees,culturalconcerns,truthtelling,online business practices, conflicts of interest, referral, vendor relationships, treatment of familymembers,sexualrelationships,fatality. **10hrs**

UNIT–IV

CPCSEAguidelinesforlaboratoryanimalfacility:Goals,veterinarycare,quarantine,surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animalfacilitiestolaboratories,anesthesia,euthanasia,physicalfacilities,environment,animalhusbandry,recordkeeping,SOPs,personneland training,transportoflabanimals.10 hrs

UNIT–V

DeclarationofHelsinki:History,introduction,basicprinciplesforallmedicalresearch,and additionalprinciples formedicalresearchcombinedwithmedicalcare.

10hrs

Reference Books

1. PhilipKotlerandKevinLaneKeller:MarketingManagement,PrenticeHallofIndia,NewDelhi.
2. ArunKumar,Meenakshi:MarketingManagement,VikasPublishing,india

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(Approved by AICTE & PCI, New Delhi & affiliated to Kakatiya University , Warangal, T.S)
Ramnagar Dist. Hanumakonda- 506001, (T.S)

Subject: Pharmaceutical analysis-I

Program Name: B. Pharmacy

Year/Sem: I-SEM

Theory/Lab: Theory

LESSON PLAN

S.NO	Topics to be covered	Hours Required
	UNIT -I	
1.	Pharmaceutical analysis- Scope- a) Techniques of analysis b) Expressing concentration c) Preparation and standardization of molar and normal solutions	3
2.	Errors- Sources, types, methods of minimizing errors, precision and significant figures	3
3.	Pharmacoepia,sources of impurities in medicinal agents	2
	UNIT -II	
1.	Acid-Base Titration Acid base indicators, acid base titrations	3
2.	Titrations involved in strong, weak and very weak acids and bases	3
3.	Neutralization curves	2
4.	Non-aqueous titrations Solvents, acidimetry and alkalimetry	3
5.	Estimation of sodium benzoate and ephedrine HCL	2
	UNIT –III	
1.	Precipitation titrations Mohr's ,volhard's, modified volhard's,fajan's methods	2
2.	Estimation of sodium chloride	1
3.	Complexometric titrations Classification, metal ion indicators, masking and demasking agents	2
4.	Estimation of magnesium sulphate and calcium gluconate	2
5.	Gravimetry Principle, steps involved in gravimetric analysis	2
6.	Co-precipitation and post precipitation, estimation of barium sulphate	2
7.	Basic principles and methods and applications of diazotization titrations	2
	UNIT -IV	
1.	Redox titrations	2

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	Concepts of Oxidation and reduction	
2.	Types of redox titrations (principles and applications) ceremetry, iodometry and iodimetry, bromatometry, dichrometry	3
	UNIT -V	
1.	Electro chemical method of analysis Conductometry- conductivity cell, titrations and applications	3
2.	Potentiometry- Electrochemical cell, construction and working of reference &indicator electrodes	3
3.	Method to determine end point of potentiometric titrations and applications	2
4.	Polarography Principle, Ilkovic's equation, construction and working of dropping mercury electrode & rotating platinum electrode	3

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Ramnagar Dist. Hanumakonda- 506001, (T.S)

Subject: Social and Preventive Pharmacy

Program Name: B. Pharmacy

Year/Sem: VIII-SEM

Theory/Lab: Theory

LESSON PLAN

S.NO	Topics to be covered	Hours Required
	UNIT -I	
1.	Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease	2
2.	social causes of diseases and social problems of the sick	2
3.	Food in relation to nutrition and health, Balanced diet	2
4.	Food in relation to Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.	2
5.	Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health	2
6.	Personal hygiene and health care; avoidable habits	1
	UNIT -II	
1.	Pharmaco dynamics- Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors.	2
2.	SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue,	3
3.	lymphatic filariasis, pneumonia	2
4.	hypertension, diabetes mellitus	2
5.	Cancer	2
6.	drug addiction-drug substance abuse	1
	UNIT –III	
1.	National health programs, its objectives, functioning and outcome of HIV AND AIDS control programme	2
2.	National health programs, its objectives, functioning and outcome of TB, Integrated disease surveillance program (IDSP)	2
3.	National health programs, its objectives, functioning and outcome of National leprosy control programme	2
4.	National mental health program, National programme for prevention and control of deafness	2
5.	Universal immunization programme	2
6.	National programme for control of blindness	1
7.	National programme for control of Pulse polio programme	1

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	UNIT -IV	
1.	National health intervention programme for mother and child	2
2.	National family welfare Programme	1
3.	National tobacco control Programme	1
4.	National Malaria Prevention Program	1
5.	National Programme for the health care for the elderly, Social health programme	2
6.	Role of WHO in Indian national program	1
	UNIT -V	
1.	Community services in rural, urban and school health	1
2.	Functions of PHC Improvement	1
3.	National urban health mission	1
4.	Health promotion education in School	1
5.	Health promotion in School	1

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Ramnagar Dist. Hanumakonda- 506001, (T.S)

Subject: Pharmacology –II

Program Name: Pharm.D

Year/Sem: Third Year

Theory/Lab: Theory

LESSON PLAN

S.NO	Topics to be covered	Hours Required
	UNIT -I	
1.	Pharmacology of Drugs acting on Blood and blood forming agents Anticoagulants	2
2.	Pharmacology of Drugs acting on Blood and blood forming agents Thrombolytics and antiplatelet agents	2
3.	Pharmacology of Drugs acting on Blood and blood forming agents Haemopoietics and plasma expanders	2
	UNIT -II	
1.	Pharmacology of drugs acting on Renal System a) Diuretics	2
2.	Pharmacology of drugs acting on Renal System b) Antidiuretics	2
	UNIT –III	
1.	**Chemotherapy** a) Introduction b) Sulfonamides and co-trimoxazole	2
2.	Penicillins and Cephalosporins	2
3.	Tetracyclins and Chloramphenicol Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics Quinolines and Fluroquinolines	4
4.	Antifungal antibiotics Antiviral agents Chemotherapy of tuberculosis and leprosy	4
5.	Chemotherapy of Malaria Chemotherapy of protozoal infections (amoebiasis, Giardiasis) Pharmacology of Anthelmintic drugs Chemotherapy of cancer (Neoplasms)	4

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	UNIT -IV	
1.	Pharmacology of immunosuppressants	2
2.	Immunopharmacology Pharmacology of stimulants	3
	UNIT -V	
1.	Principles of Animal toxicology Acute, sub acute	2
2.	Principles of Animal toxicology, chronic toxicity	2
	UNIT –VI	
1.	Cell and macromolecules: Cellular classification, subcellular organelles, macromolecules, large macromolecular assemblies	3
2.	Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information	3
3.	DNA replication: General, bacterial and eukaryotic DNA replication.	2
4.	The cell cycle: Restriction point, cell cycle regulators and modifiers.	2
5.	Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways	3
6.	Gene structure: Organization and elucidation of genetic code.	2
7.	Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression	3
8.	Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes	3
9.	Transcription factors that regulate transcription in pro and eukaryotes.	2
10.	RNA processing: rRNA, tRNA and mRNA processing.	2
11.	Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events	3
12.	Altered gene functions: Mutations, deletions, amplifications, LOH, traslocations, trinucleotide repeats and other genetic abnormalities.	3
13.	Oncogenes and tumor suppressor genes.	2

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Ramnagar Dist. Hanumakonda- 506001. (T.S)

Subject: Human Anatomy and Physiology

Program Name: Pharm.D

Year/Sem: First Year

Theory/Lab: Theory

LESSON PLAN

S.NO	Topics to be covered	Hours Required
	UNIT -I	
1.	Scope of anatomy and physiology	1
2.	Levels of Structural Organization and Body Systems	1
3.	Basic Anatomical Terminology	1
	UNIT -II	
1.	Structure of cell – its components and their functions	2
2.	The processes that transport substances across the plasma membrane	1
	UNIT -III	
1.	The structure and functions of the five main types of cell junctions	2
2.	Epithelial tissues	2
3.	Connective tissues	1
4.	Muscular tissues and Nervous tissue	1
	UNIT -IV	
1.	Bone Tissue	2
2.	Axial System	2
3.	Appendicular system	2
4.	Classification and Types of Movements of Joints	2
5.	Disorders of joints	1
	UNIT -V	
1.	Functions and Properties of Blood	1
2.	Formation, Anatomy and Physiology of Blood Cells- RBC, WBC and platelets	2
3.	Hemostasis- Vascular Spasm; Platelet Plug Formation; Mechanism and factors effecting blood clotting	2
4.	Blood groups and their significance	1
5.	Disorders of platelets and coagulation, Definitions of Disorders of Blood components	2
	UNIT -VI	
1.	Structure and functions of lymphatic system- Lymphatic Vessels and Lymph Circulation.	2
2.	Lymphatic Organs and Tissues-thymus, lymph nodes, spleen, lymph nodules, MALT	3
3.	Disorders of lymph and lymphatic system	2

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	UNIT -VII	
1.	Overview of CVS	1
2.	Anatomy and functions of heart and heart valves	2
3.	Circulation of Blood (Pulmonary, coronary and systemic circulation)	2
4.	Electrocardiogram and its Correlation to Conduction system Heart Auscultations	2
5.	Cardiac muscle tissue and cardiac conduction system	1
6.	Cardiac cycle and factors affecting it	1
7.	Cardiac output and factors affecting it	1
8.	Structure of Blood Vessels	1
9.	Blood pressure – its maintenance and regulation	2
10.	Definition of the following disorders: Hypertension, Hypotension, Arteriosclerosis, Atherosclerosis, Angina, Myocardial infarction, Congestive heart failure, Cardiac arrhythmias.	2
	UNIT -VIII	
1.	Anatomy & Functions of Respiratory Organs	1
2.	Mechanism/Physiology of Respiration- Pulmonary ventilation (mechanism and regulation of Respiration)	2
3.	Exchange and transport of oxygen and carbon dioxide	1
4.	Control of respiration	1
5.	Lung Volumes and Capacities	1
6.	Definition of Hypoxia, Asphyxia, Dibarysim, Oxygen therapy, resuscitation.	1
	UNIT -IX	
1.	Overview of the Digestive System	1
2.	Layers of the GI Tract Neural Innervation of the GI Tract Anatomy and functions peritoneum	2
3.	Anatomy and functions of Salivary gland, tongue and teeth. Mechanical and Chemical Digestion in the Mouth	2
4.	Anatomy and functions of pharynx	1
5.	Anatomy, Histology and Physiology of esophagus, Deglutination reflex	1
6.	Anatomy and Histology of Stomach, Mechanical and Chemical Digestion in the Stomach.	2
7.	Anatomy and Histology of Pancreas, Composition and Functions of Pancreatic Juice.	1
8.	Anatomy, Histology and Functions of liver & gall bladder.	1
9.	Anatomy and Histology of small intestine, Role of Intestinal Juice and Brush-Border Enzymes, Mechanical, chemical digestion and absorption of food in small intestine.	2
10.	Anatomy and Histology of large intestine, Mechanical, chemical digestion, absorption of food and Feces Formation in large intestine.	1
11.	Different types of GI motility	1
12.	Disorders of GIT	1
	UNIT -X	
1.	Overview of Nervous system Classification of nervous system	1
2.	Structure of Neuron and types of neurons	1
3.	Myelination of Neurons	1
4.	Structure and types of neuroglia cells	1
5.	Generation and propagation of Graded Potential and Action Potential	1

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6.	Signal transmission at synapse. Neurotransmitters in CNS.	1
7.	Brain Organization, Protection, and Blood Supply	1
8.	Formation and Functions of CSF	1
9.	Anatomy, physiology and functional areas of cerebrum	1
10.	Anatomy and physiology of cerebellum	1
11.	Anatomy and physiology of mid brain	1
12.	Anatomy and physiology of Thalamus, hypothalamus and Basal Ganglia	1
13.	Classification of Cranial nerves, their origin, innervation, transmission and functions	1
14.	Anatomy and physiology of spinal cord.	1
15.	Classification of Spinal nerves, their origin, innervation, transmission and functions	1
16.	Spinal Arc and Spinal Reflexes	1
17.	Anatomy of Sympathetic and Parasympathetic nervous system	1
18.	ANS Neurotransmitters-Physiological effects of ANS neurotransmitters	1
19.	Deference between Sympathetic and parasympathetic nervous system	1
20.	Autonomic reflexes	1
	UNIT -XI	
1.	Overview of Kidney Functions	1
2.	External Anatomy and Histology of the Kidneys	1
3.	External Anatomy and Histology of the nephron	1
4.	Renal Physiology (Physiology of Urine Formation)	1
5.	Renin Angiotensin system- Jextaglomerular apparatus	1
6.	Acid-base balance	1
7.	Clearance tests and micturition	1
	UNIT -XII	
1.	Overview of Endocrine system and Endocrine glands	1
2.	Principles of hormone activity	1
3.	Mechanism of hormone action	1
4.	Control of hormone secretion	1
5.	Structure, Secretions & Functions of hypothalamus & pituitary gland.	1
6.	Pitutary hormones, their physiological functions, their control by hypothalamus	2
7.	Anatomy of Thyroid gland. Formation, secretion and regulation of secretion of thyroid hormones and their functions, diseases of the thyroid.	2
8.	Structure and hormone secreted by parathyroid gland. Parathromone and calcitonin, control of calcium metabolism. Abnormalities of Parathromone and calcitonin secretion.	1
9.	Anatomy of Adrenal gland. Adrenocortical hormones, secretion, regulation and functions. Abnormalities of adrenal secretion.	1
10.	Pancreatic islets structure, effects of pancreatic hormones. Abnormalities of pancreatic secretion.	1
	UNIT –XIII	
1.	Male reproductive system	1
2.	Female reproductive system	1
3.	Hormones secreted by Reproductive system	1
4.	Physiology of menstruation	1

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5.	Spermatogenesis & Oogenesis	1
6.	Sex determination (genetic basis)	1
7.	Pregnance and maintenance and parturition	1
8.	Contraceptive devices	1
	UNIT –XIV	
1.	Olfaction: Sense of Smell (Anatomy of Olfactory receptors, physiology of Olfaction, odor thresholds and adaptation;olfactory pathway).	1
2.	Gustation: Sense of Taste	1
3.	Vision and Disorders of vision	1
4.	Hearing and Equilibrium and disorders of hearing.	1
5.	Skin (Anatomy, Functions and Disorders)	1
	UNIT –XV	
1.	Histology of skeletal muscle	1
2.	Physiology of Muscle contraction	1
3.	Physiological properties of skeletal muscle	1
4.	Disorders of skeletal muscle (definitions)	1
	UNIT –XVI	
1.	Muscles in exercise, Effect of athletic training on muscles and muscle performance	1
2.	Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,	1
3.	Drugs and athletics	1

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Ramnagar Dist. Hanumakonda- 506001, (T.S)

Subject: Medicinal Chemistry

Program Name: Pharm.D

Year/Sem: Third Year

Theory/Lab: Theory

LESSON PLAN

S.No	Topics to be covered	Hours Required
	UNIT -I	
1.	Modern concept of rational drug design: QSAR	2
2.	Prodrug	2
3.	Combinatorial Chemistry	2
4.	CADD	3
5.	Antisense Molecules	1
	UNIT -II	
1.	Anti infective agents : Local anti infective agents	2
2.	Preservatives	2
3.	Antifungal agents	3
4.	Urinary tract anti infective agents	3
5.	Anti tubercular agents	2
6.	Anti viral and anti AIDS agents	3
7.	Antiprotozoal agents	2
8.	Anthelmintics	2
9.	Antiscabies and antipedicular agents	2
	UNIT -III	
1.	Sulphonamide and sulphones	3
	UNIT -IV	
1.	Antimalarials	3
	UNIT -V	
1.	Antibiotics	4
	UNIT -VI	
1.	Antineoplastic agnts	4
	UNIT -VII	
1.	Cardiovascular agents: Antihypertensive agents	3
2.	Antianginal and vasodilator agents	3
3.	Antiarrhythmic agents	3
4.	Antihyperlipidemic agents	3
5.	Coagulants and anticoagulants	2
6.	Endocrine	2
	UNIT -VIII	

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1	Hypoglycemic agents	3
	UNIT -IX	
1.	Thyroid and antithyroid agents	3
	UNIT -X	
1.	Diuretics	3
	UNIT -XI	
1.	Diagnostic agents	2
	UNIT -XII	
1.	Steroidal hormones and Adrenocorticoids	3

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Ramnagar Dist. Hanumakonda- 506001, (T.S)

Subject: Pharmacetical Organic Chemistry

Program Name: Pharm.D

Year/Sem: First Year

Theory/Lab: Theory

LESSON PLAN

S.No	Topics to be covered	Hours Required
	UNIT -I	
1.	Structures and Physical Properties : Polarity of bonds, polarity of molecules	1
2.	M.P, Inter molecular forces, B.P, Solubility	2
3.	Non ionic solutes and ionic solutes	1
4.	Protic and aprotic solvents, ion pairs	1
5.	Acids and bases, Lowry bronsted and Lewis Theories	2
6.	Isomerism	2
	UNIT -II	
1.	Nomenclature of organic compounds : Alkanes, Alkenes, Dienes, Alkynes	2
2.	Carboxylic Acid, Esters, Acid Chlorides, Acid amides	1
3.	Aldehydes, Ketones, Amines, Alcohols, Phenols	1
4.	Alkyl halides, Cycloalkanes	1
	UNIT -III	
1.	Free radicals chain reactions of alkane : Free radical mechanism	2
2.	Relative reactivity of free radicals	1
3.	Stability of free radicals	1
	UNIT -IV	
1.	Alicyclic compounds : Preparations of cyclo alkanes	1
2.	Bayer strain theory	1
3.	Orbital picture of angle strain	1
	UNIT -V	
1.	Nuclophilic aliphatic Substitution : Nucleophiles and leaving groups	1
2.	Mechanism & kinetics of SN_2 reactions	2
3.	Mechanism & kinetics of SN_1 reactions	2
4.	Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis of SN_2 reactions	2
5.	Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis of SN_1 reactions	2
6.	SN_2 versus SN_1	1
	UNIT -VI	
1.	Dehydro halogenations of alkyl halides : 1,2 elimination, kinetics	1

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2.	E2 and E1 mechanism	2
3.	Elimination via carbocation, evidence for E2 mechanism, absence of rearrangement, isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity	3
4.	E2 versus E1	1
5.	Elimination versus substitution	1
6.	Dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation	1
	UNIT -VII	
1.	Electrophillic and free radicals addition: Reactions at carbon-carbon single bond and double bond, electrophiles	1
2.	Hydrogenation, heat of hydrogenation and stability of alkenes	1
3.	Markownikoff rule, addition of hydrogen halides	2
4.	Addition of hydrogen bromides, peroxide effect	1
5.	Electrophillic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity	2
6.	Addition of halogen, mechanism, halohydin formation	1
7.	Mechanism of free radical addition reaction	1
8.	Mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition	1
9.	Additions of carbene to alkene, cyclo addition Reactions	1
	UNIT -VIII	
1.	Free radical substitution reactions: Carbon-carbon double bond as substituents	1
2.	Free radical halogenations of alkenes	3
3.	Comparison of free radical substitution with free radical addition	1
4.	Free radical substitution in alkenes, orientation and reactivity, allylic rearrangements	1
	UNIT -IX	
1.	Theory of resonance : Allyl radical as a resonance hybrid	1
2.	Stability, orbital picture, resonance stabilization of allyl radicals	2
3.	Hyper conjugation, Nucleophilic substitution in allylic substrate	1
4.	SN_1 reactivity, allylic rearrangement, resonance stabilization of allyl cation	1
5.	SN_2 nucleophilic substitution in vinylic substrate	1
	UNIT -X	
1.	Electrophilic aromatic Substitution: Mechanism, Orientation and relative reactivity	2
2.	Substituent groups and its effects	1
3.	Nitration, sulphonation, halogenation, friedel craft alkylation, friedel craft acylation	2

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4.	Activating and deactivating O,P,M directing groups	2
5.	Effect of halogen on electrophilic aromatic substitution in alkyl benzene	1
6.	Side chain halogenation of alkyl benzene, resonance stabilization of benzyl radical	1
	UNIT -XI	
1.	Nucleophilic addition Reaction: Mechanism of nucleophilic addition reaction	1
2.	Acidity of carboxylic acids	1
3.	Ionization of carboxylic acids, acidity constants	1
4.	Structure of carboxylate ions, effect of substituent on acidity	1
5.	Nucleophilic acyl substitution reaction	1
6.	Conversion of acid to acid chloride, esters, amide and anhydride	1
7.	Role of caboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution	1
	UNIT -XII	
1.	Named reactions : Aldol condensation and crossed aldol condensation	1
2.	Cannizzaro reaction and crossed cannizzaro Reaction	1
3.	Claisen condensation and benzoin condensation	1
4.	Perkin condensation, knoevenagel, reformatsky Reaction	1
5.	Wittig reaction, michael addition	1
	UNIT -XIII	
1.	Amines & phenols : Basicity of amines, Preparation of amine-Hoffmann rearrangement reaction	2
2.	Diazotisation and coupling reactions	2
3.	Acidity of phenols	1
4.	Williamson synthesis, Fries rearrangement	1
5.	Kolbe reaction, Reimer tieman's reactions	1
	UNIT -IV	
1.	Nucleophilic aromatic substitution reactions : Bimolecular displacement mechanisms & Orientation	1
2.	Comparison of aliphatic nucleophilic substitution with that of aromatic	1
	UNIT -V	
1.	Oxidation & reduction Reactions : Oxidation-Definitions, different oxidizing agents & Applications	1
2.	Reduction-Definitions, different reducing agents & Applications	1
	UNIT -VI	
1.	Preparation, test for purity, assay and medicinal uses of some official Compounds: Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea	1
2.	Ethylene diamine dihyrate, vanillin, paraldehyde, ethylene chloride	1
3.	Lactic acid, tartaric acid, citric acid, salicylic acid, aspirin	1
4.	Methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl pthalate, sodium lauryl sulphate	1
5.	Saccharin sodium & mephensin	1

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Ramnagar Dist. Hanumakonda- 506001, (T.S)

Subject: Pharmacetical Organic Chemistry -I | Program Name: B.Pharm

Year/Sem: II SEM | Theory/Lab: Theory

LESSON PLAN

S.No	Topics to be covered	Hours Required
	UNIT -I	
1.	**Classification, nomenclature and isomerism :** Classification of Organic Compounds	1
2.	Common system of nomenclature of organic compounds	1
3.	IUPAC system of nomenclature of organic compounds	1
4.	Structural isomerisms in organic compounds	1
	UNIT -II	
1.	**Alkanes, Alkenes and Conjugated dienes:** Introduction to Alkanes, preparations & reactions	2
2.	Introduction to Alkenes, preparations & reactions	2
3.	Introduction to conjugated dienes, preparations & reactions	2
4.	Hybridization concept introduction	2
	UNIT -III	
1.	**Alkyl halides:** Introduction to Alkanes, preparations & reactions	2
2.	SN1 and SN2 reactions	2
3.	E1 and E2 reactions	2
4.	Structure and uses of selected alkyl halides	1
5.	**Alcohols :** Introduction to Alcohols, preparations & reactions	2
6.	Qualitative & Distinguishing tests	1
7.	Structure and uses of selected alcohols	1
	UNIT -IV	
1.	**Carbonyl compounds (Aldehydes and ketones):** Introduction to Aldehydes, preparations & reactions	2

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2.	Qualitative & Distinguishing tests	2
3.	Introduction to ketones, preparations & reactions	6
4.	Qualitative & Distinguishing tests	1
5.	Named reactions: mechanism and applications	2
	UNIT -V	
1.	**Carboxylic acids :** Introduction to carboxylic acids, preparations & reactions	2
2.	Qualitative tests	1
3.	Structure and uses of selected carboxylic acids	1
4.	Introduction to amides and esters	1
5.	Introduction to aliphatic amines, preparations & reactions	2
6.	Qualitative & Distinguishing tests	1
7.	Structure and uses of selected aliphatic amines	1

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Ramnagar Dist. Hanumakonda- 506001, (T.S)

Subject: Bio Chemistry

Program Name: B.Pharm

Year/Sem: II SEM

Theory/Lab: Theory

LESSON PLAN

S.No	Topics to be covered	Hours Required
	UNIT -I	
1.	Biomolecules: Introduction, classification, chemical nature and biological role of carbohydrate, lipids, nucleic acids, amino acids and proteins	4
2.	Bioenergetics: Concept of free energy, endergonic and exergonic reaction, Relationship between free energy, enthalpy and entropy; Redox potential	2
	UNIT -II	
1.	Carbohydrate metabolism : Glycolysis – Pathway, energetics and significance	1
2.	Citric acid cycle- Pathway, energetics and significance	1
3.	HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency	1
4.	Glycogen metabolism Pathways and glycogen storage diseases (GSD) Gluconeogenesis- Pathway and its significance	2
5.	Hormonal regulation of blood glucose level and Diabetes mellitus	1
6.	**Biological oxidation :** Electron transport chain (ETC) and its mechanism	1

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7.	Oxidative phosphorylation & its mechanism and substrate level phosphorylation	2
8.	Inhibitors ETC and oxidative phosphorylation/Uncouplers	1
	UNIT -III	
1.	**Lipid metabolism :** β-Oxidation of saturated fatty acid (Palmitic acid) Formation and utilization of ketone bodies; ketoacidosis	2
2.	De novo synthesis of fatty acids (Palmitic acid)	2
3.	Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D	2
4.	Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity	2
5.	**Amino acid metabolism :** General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders	2
6.	Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenyketonuria, Albinism, alkeptonuria, tyrosinemia)	2
7.	Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline	1
8.	Catabolism of heme; hyperbilirubinemia and jaundice	1
	UNIT -IV	
1.	**Nucleic acid metabolism and genetic information transfer :** Biosynthesis of purine and pyrimidine nucleotides	2
2.	Catabolism of purine nucleotides and Hyperuricemia and Gout disease	2
3.	Organization of mammalian genome	1
4.	Structure of DNA and RNA and their functions	1
5.	DNA replication (semi conservative model)	1
6.	Transcription or RNA synthesis	1
7.	Genetic code, Translation or Protein synthesis and inhibitors	2

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	UNIT -V	
1.	Enzymes : Introduction, properties, nomenclature and IUB classification of enzymes	1
2.	Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)	2
3.	Enzyme inhibitors with examples	1
4.	Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation	1
5.	Therapeutic and diagnostic applications of enzymes and isoenzymes; Coenzymes – Structure and biochemical functions	2

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Ramnagar Dist. Hanumakonda- 506001, (T.S)

Subject: Pharmacetical Organic Chemistry -II | Program Name: B.Pharm

Year/Sem: III SEM | Theory/Lab: Theory

LESSON PLAN

S.No	Topics to be covered	Hours Required
	UNIT -I	
1.	Benzene and its derivatives: A. Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule	3
2.	B. Reactions of benzene - nitration, sulphonation, halogenation- reactivity, Friedelcrafts alkylation-reactivity, limitations, Friedelcrafts acylation.	4
3.	C. Substituents- effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction	2
4.	D.Structure and uses of DDT, Saccharin, BHC and Chloramine	1
	UNIT -II	
1.	Phenols: Acidity of phenols, effect of substituents on acidity, qualitative tests	2
2.	Methods of preparation and reactions of Phenol	2
3.	Structure and uses of phenol, cresols, resorcinol, naphthols	1
4.	Aromatic amines: Basicity of amines, effect of substituents on basicity,	1
5.	Methods of preparation and reactions of Aromatic amines	2
6.	Synthetic uses of aryl diazonium salts	2
7.	**Aromatic Acids :** Acidity, effect of substituents on acidity and important reactions of benzoic acid.	2

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	UNIT -III	
1.	Fats and Oils : a.Fatty acids – reactions	1
2.	b. Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils	3
3.	c. Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination	6
	UNIT -IV	
1.	Polynuclear hydrocarbons: Synthesis, Reactions & Structure of Naphthalene, Phenanthrene, and medicinal uses of their	4
2.	Synthesis, Reactions & Structure of Anthracene, Diphenylmethane and medicinal uses of their derivatives	3
3.	Synthesis, Reactions & Structure of Triphenylmethane and medicinal uses of their derivatives	3
	UNIT -V	
1.	Cycloalkanes : Stabilities – Baeyer's strain theory, limitation of Baeyer's strain theory	2
2.	Coulson and Moffitt's modification, Sachse Mohr's theory (Theory of strainless rings)	2
3.	Methods of preparations &Reactions of cyclopropane and cyclobutane only	2

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Ramnagar Dist. Hanumakonda- 506001, (T.S)

Subject: Pharmacetical Organic Chemistry -III | Program Name: B.Pharm

Year/Sem: IV SEM | Theory/Lab: Theory

LESSON PLAN

S.No	Topics to be covered	Hours Required
	UNIT -I	
1.	Stereoisomerism : Optical isomerism, enantiomerism,diastereomerism and Meso compounds	4
2.	Chirality, Elements of symmetry	2
3.	D&L configurations	1
4.	Sequence rules and R&S configurations	2
5.	Racemic modifications and its resolutions	2
6.	Asymmetric synthesis- partial and absolute	2
	UNIT -II	
1.	Geometrical isomerism : Cis-Trans, E&Z and Syn-anti configurations	2
2.	Methods of determination of configuration of geometrical isomers	1
3.	Conformational isomerism in Ethane, n-Butane and Cyclohexane	3
4.	Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity	2
5.	Stereospecific and stereoselective reactions	2
	UNIT -III	
1.	Heterocyclic compounds : Nomenclature and classification	2

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2.	Synthesis, reactions and medicinal uses of Pyrrole, Furan, and Thiophene	2
3.	Relative aromaticity, reactivity and Basicity of pyrrole	1
	UNIT -IV	
1.	Synthesis, reactions and medicinal uses of Pyrazole, Imidazole, Oxazole and Thiazole	4
2.	Synthesis, reactions and medicinal uses of Pyridine, Quinoline, Isoquinoline, Acridine and Indole	4
3.	Basicity of pyridine	1
4.	Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives	3
	UNIT -V	
1.	Reactions of synthetic importance : Metal hydride reduction (NaBH4 and LiAlH4)	2
2.	Clemmensen reduction, Birch reduction, Wolff Kishner reduction	3
3.	Oppenauer-oxidation and Darkin reaction	2
4.	Beckmanns rearrangement and Schmidt rearrangement	2
5.	Claisen- Schmidt condensation	1

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Ramnagar Dist. Hanumakonda- 506001, (T.S)

Subject: Medicinal Chemistry-I | Program Name: B.Pharm

Year/Sem: IV SEM | Theory/Lab: Theory

LESSON PLAN

S.No	Topics to be covered	Hours Required
	UNIT -I	
1.	Introduction to medicinal chemistry: History and Development of medicinal chemistry	2
2.	Physico chemical properties	4
3.	Drug Metabolism	4
	UNIT -II	
1.	Drugs acting on Autonomic Nervous system- Sympathetic Agents: Adrenergic neurotransmitters	2
2.	Sympathomimetic agents	4
3.	Sympatholytic agents	4
	UNIT -III	
1.	Drugs acting on Autonomic Nervous system- Parasympathetic Agents: Cholinergic Neurotransmitters	2
2.	Parasympathomimetic agents	4
3.	Parasympatholytic agents	4
	UNIT -IV	

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1.	Drugs acting on central nervous system 1: Sedatives and hypnotics	3
2.	Antipsychotics	3
3.	Anticonvulsants	2
	UNIT -V	
1.	Drugs acting on central nervous system 2 : General anesthetics	2
2.	Narcotic and non narcotic analgesics	2
3.	Anti inflammatory agents	3

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(Approved by AICTE & PCI, New Delhi & affiliated to Kakatiya University , Warangal, T.S)
Ramnagar Dist. Hanumakonda- 506001, (T.S)

Subject: Medicinal Chemistry-II

Program Name: B.Pharm

Year/Sem: V SEM

Theory/Lab: Theory

LESSON PLAN

S.No	Topics to be covered	Hours Required
	UNIT -I	
1.	Antihistaminic agents: Histamine receptors and distribution	1
2.	H1 Antagonists	2
3.	H2 Antagonists	1
4.	Gastric proton pump inhibitors	1
5.	Antineoplastic agents: Alkylating agents	2
6.	Antimetabolites	1
7.	Antibiotics	1
8.	Plant products and miscellaneous	1
	UNIT -II	
1.	Antianginals: Vasodilators	2
2.	Calcium channel blockers	2
3.	Diuretics	3
4.	Antihypertensive agents: Classification , antihypertensive drugs	3
	UNIT -III	
1.	Antiarrythmic drugs:	4
2.	Antihyperlipidemic agents	2
3.	Coagulants and anticoagulants	2
4.	Drugs used in CHF	1
	UNIT -IV	

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1.	Drugs acting on endocrine system: Sex hormones	1
2.	Drugs for erectile dysfunction	1
3.	Oral contraceptives	2
4.	corticosteroids	2
5.	Thyroid and antithyroid drugs	2
	UNIT -V	
1.	Antidiabetic agents: Insulin and its preparations	2
2.	Local anesthetics: SAR	1
3.	Benzoic acid derivatives	1
4.	Amino benzoic acid derivatives	1
5.	Lidocaine/anilide derivatives	1
6.	Miscellaneous	1

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Ramnagar Dist. Hanumakonda- 506001, (T.S)

Subject: Medicinal Chemistry-III | Program Name: B.Pharm

Year/Sem: VI SEM | Theory/Lab: Theory

LESSON PLAN

S.No	Topics to be covered	Hours Required
	UNIT -I	
1.	Antibiotics: Introduction	2
2.	Beta lactam antibiotics	3
3.	Aminoglycosides	3
4.	Tetracyclins	2
	UNIT -II	
1.	Macrolide antibiotics	2
2.	Prodrugs: Concepts, Application	2
3.	Antimalarials : Etiology of malaria	1
4.	Quinolones	2
5.	Biguanides and dihyrotriazines	2
6.	Miscellaneous	1
	UNIT -III	
1.	Antitubercular agents : Synthetic antitubercular agents	2
2.	Antitubercular antibiotics	2
3.	Urinary tract antiinfective agents: Quinolones	2
4.	Miscellaneous	2
5.	Antiviral agents	2
	UNIT -IV	
1.	Antifungal agents : Antifungal antibiotics	2
2.	Synthetic antifungal agents	2
3.	Anti protozoal agents	2
4.	Anthelmintics	1
5.	Sulphonamides and Sulfones	1
	UNIT -V	
1.	Introduction to Drug design, Various approaches	2
2.	Physiochemical parameters	2
3.	Pharmacophore modeling and docking techniques	1
4.	Combinatorial chemistry: Concepts and Applications	2

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Ramnagar Dist. Hanumakonda- 506001, (T.S)

Subject: Biopharmaceutics and Pharmacokinetics
Year/Sem: VI SEM

Program Name: B.Pharm
Theory/Lab: Theory

LESSON PLAN

S.No	Topics to be covered	Hours Required
	UNIT -I	
1.	Introduction to Biopharmaceutics: Mechanisms of drug absorption through GIT	1
2.	Factors influencing drug absorption though GIT	3
3.	Absorption of drug from Non per oral extravascular routes	1
4.	Distribution of drugs Tissue permeability of drugs and binding of drugs	2
5.	Protein binding of drugs, factors affecting protein drug binding and Kinetics of protein binding	2
6.	Clinical significance of protein binding of drugs, Apparent volume of drug distribution	1
	UNIT -II	
1.	Biotransformation : Phase I Bioransformaion	2
2.	Phase II Bioransformaion	2
3.	Renal excretion of drugs, factors affecting renal excretion of drugs	1
4.	Renal clearance and Non renal routes of drug excretion of drugs	1
5.	Objectives of bioavailability studies, absolute and relative bioavailability, measurement of bioavailability	1
6.	In-vitro drug dissolution models, in- vitro, in-vivo Correlations	1
7.	bioequivalence studies, methods to enhance the bioavailability	2
	UNIT -III	
1.	Pharmacokinetics : Introduction to Pharmacokinetics models ,Compartment model	2
2.	Non compartment models, physiological models	1
3.	One compartment open model Intravenous Injection (Bolus)	2
4.	One compartment open model Intravenous infusion	1
5.	One compartment open model extra vascular Administrations	2
6.	calculations KE from plasma and urinary excretion data	2
	UNIT -IV	

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1.	Multicompartment models : Two compartment open model. IV bolus	2
2.	Multiple – Dosage Regimens	2
3.	Repititive Intravenous injections – One Compartment Open Model	2
4.	Repititive Extravascular dosing – One Compartment Open model	2
5.		
	UNIT -V	
1.	Nonlinear Pharmacokinetics: Introduction	1
2.	Factors causing Non-linearity	3
3.	Michaelis-menton method of estimating parameters	3

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Ramnagar Dist. Hanumakonda- 506001, (T.S)

Subject: Industrial Pharmacy | Program Name: B.Pharm

Year/Sem: VII SEM | Theory/Lab: Theory

LESSON PLAN

S.No	Topics to be covered	Hours Required
	UNIT -I	
1.	Pilot plant scale up techniques: General considerations	3
2.	Documentation	2
3.	SUPAC guidelines	3
4.	Introduction to Platform technology	2
	UNIT -II	
1.	Technology development and transfer: WHO guidelines for Technology Transfer	1
2.	Granularity of TT Process	2
3.	Premises and equipments	2
4.	Quality control	1
5.	Approved regulatory bodies and agencies	2
6.	TOT agencies in India	2
	UNIT -III	
1.	Regulatory affairs : Introduction	3
2.	Regulatory authorities	3
3.	Regulatory requirements for drug approval	4
	UNIT -IV	
1.	Indian Regulatory Requirements : Central Drug Standard Control Organization (CDSCO)	2
2.	State Licensing Authority	3
3.	Certificate of Pharmaceutical Product (COPP)	3
	UNIT -V	
1.	Industrial Safety : Plant Location & layout	2
2.	Hazards	3
3.	Accident records	2

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Subject: Novel Drug Delivery System | Program Name: B.Pharm

Year/Sem: VII SEM | Theory/Lab: Theory

LESSON PLAN

S.No	Topics to be covered	Hours Required
	UNIT -I	
1.	Controlled drug delivery systems	6
2.	Polymers	4
	UNIT -II	
1.	Microencapsulation	3
2.	Mucosal Drug Delivery system	4
3.	Implantable Drug Delivery Systems	3
	UNIT -III	
1.	Transdermal Drug Delivery Systems	3
2.	Gastroretentive drug delivery systems	4
3.	Nasopulmonary drug delivery system	3
	UNIT -IV	
1.	Nanotechnology and its Concepts	8
	UNIT -V	
1.	Ocular Drug Delivery Systems	7

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VAAGDEVI COLLEGE OF PHARMACY

RAMNAGAR, HANAMKONDA

B.Pharmacy I Sem Section-A 2023-24

Day/ Time	I	II	III	IV	LUNCH: 12:30to01:10PM	Practical V	VI	VII	VIII
	09:10–10:00 AM	10:00–10:50 AM	10:50-11:40 AM	11:40–12:30 PM		01:10 – 4:30 PM			
Mon	HAP-I (CHM)	P'Ceutics-I (MS)	Tutorial PIC	RB/RM (GM/KSR)		PA-I Lab B-1 (UT) P'Ceutics-I Lab B-2 (MS)			
Tue	HAP-I (CHM)	Tutorial PA-I	CS (SS)	PIC (SS)		PA-I Lab B-2 (UT) P'Ceutics-I Lab B-1 (MS)			
Wed	Yoga	Tutorial HAP-I	Tutorial P'Ceutics-I	P'Ceutics-I (MM)		HAP Lab B-1(CHM) PIC Lab B-2 (SS)			
Thu	PA-I (UT)	Yoga	Communication skills Lab (SS)			HAP Lab B-2 (CHM) PIC Lab B-1 (SS)			
Fri	PA-I (UT)	PIC (SS)	HAP-I (CHM)	CS (SS)		P'Ceutics-I (MS)	Library	Remedial class	
Sat	PA-I (UT)	PIC (SS)	Remedial Biology Lab (KSR)			Library	RB/RM (GM/KSR)	Sports	Sports

P'Ceutics-I: Pharmaceutics-I- (MS)-Mrs.M.Shravanthi, PIC: Pharmaceutical Inorganic Chemistry- (SS)-Mrs.S.Sireesha, HAP-I: Human Anatomy and Physiology-I- (CHM)-Dr.Ch.Mounika, PA-I:Pharmaceutical Analysis-I-(UT)-Mrs.Uzma Tabssum, CS: Communication skills- (SS)-Mrs.Safia Sulthana, RM: Remedial Mathematics- (GM)-Mr.G.Mahender Reddy, RB:Remedial Biology- (KSR)-Dr.K.Srinivas Reddy.

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course.

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VAAGDEVI COLLEGE OF PHARMACY

RAMNAGAR, HANAMKONDA

B.Pharmacy I Sem Section-B 2023-24

Day/ Time	I	II	III	IV	LUNCH: 12:30to01:10PM	V	VI	VII	VIII
	09:10–10:00 AM	10:00–10:50 AM	10:50-11:40 AM	11:40–12:30 PM		01:10–02:00 PM	2.00-2:50 P.M	2:50-3:40 PM	3.40-4.30 PM
Mon	PA-I Lab B-3 (UT) P'Ceutics Lab B-4 (KN)					PIC (DMD)	Yoga	Tutorial PA-I	HAP-I (DM)
Tue	PA-I Lab B-4 (UT) P'Ceutics Lab B-3 (KN)					Tutorial	Tutorial P'Ceutics-I	Remedial Class	Tutorial HAP-I
Wed	HAP-I Lab B-3 (DM) PIC Lab B-4 (DMD)					PA-I (LM)	Yoga	P'Ceutics-I (KN)	Remedial class
Thu	HAP-I Lab B4 (DM) PIC Lab B-3(DMD)					PIC (DMD)	RM/RB (GM/KSR)	PA-I (LM)	P'Ceutics-I (KN)
Fri	HAP-I (UT)	CS (SS)	Remedial Biology Lab (KSR)			PIC (DMD)	RM/RB (GM/KSR)	PA-I (UT)	Tutorial PIC
Sat	HAP-I (UT)	CS (SS)	Communication skills Lab (SS)			P'Ceutics-I (KN)	Library	Sports	Sports

P'Ceutics-I: Pharmaceutics-I-(KN)-Mrs.K.Nandini , PIC: Pharmaceutical Inorganic Chemistry-(DMD)- Mrs.D.Madhuri, HAP-I: Human Anatomy and Physiology-I-(DM)- Mrs.D.Mounika, PA-I: Pharmaceutical Analysis-I-(UT)-Mrs.Uzma Tabassum, CS: Communication skills- (SS)-Mrs.Safia Sulthana, RM: Remedial Mathematic-(GM)-Mr.G.Mahender Reddy, RB:Remedial Biology- (KSR)-Dr.K.Srinivas Reddy.

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course.

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VAAGDEVI COLLEGE OF PHARMACY

RAMNAGAR, HANAMKONDA

B.Pharmacy II Sem Section-A 2023-24

Day/ Time	I	II	III	IV	LUNCH: 12:30to01:10PM	Practical V	VI	VII
	09:10–10:00 AM	10:00– 10:50 AM	10:50-11:40 AM	11:40–12:30 PM		01:10 – 4:30 PM		
Mon	HAP-II (MM)	Patho (MSL)	Tutorial	EVS (KSR)		Biochem Lab B-1 (DM) CA Lab B-2 (PR)		
Tue	HAP-II (MM)	Tutorial	CA (PR)	Biochem (DM)		Biochem Lab B-2(DM) CA Lab B-1 (PR)		
Wed	HAP-II (MM)	Tutorial	Biochem (DM)	Patho (MSL)		HAP Lab B-1(MM) POC-I Lab B-2 (LM)		
Thu	POC-I (LM)	Remedial Class	Yoga	Library		HAP Lab B-2 (MM) POC-I Lab B-1 (LM)		
Fri	POC-I (LM)	Library	EVS (KSR)	CA (PR)		Patho (MSL)	Yoga	Remedial class / Yoga
Sat	POC-I (LM)	Biochem (DM)	Tutorial	CA (PR)		Tutorial	EVS (KSR)	Sports

POC-I: Pharmaceutical Organic Chemistry-I-(LM)-Mrs.L.Maneesha, Patho: Pathophysiology-(MSL)-Mrs. M.Sumalatha, HAP-II: Human Anatomy and Physiology-II-(MM)- Mrs. M.Madhavi, Biochem: Biochemistry-(DM)-Mrs.D.Madhuri, CA: Computer Applications in Pharmacy-(PR)- Mrs. P.Ramadevi, EVS: Environmental sciences-(KSR)- Dr.K.Srinivas Reddy.

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course.

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VAAGDEVI COLLEGE OF PHARMACY

RAMNAGAR, HANAMKONDA

B.Pharmacy II Sem Section-B 2023-24

Day/ Time	I	II	III	IV	LUNCH: 12:30to01:10PM	V	VI	VII	VIII
	09:10– 10:00 AM	10:00– 10:50 AM	10:50-11:40 AM	11:40–12:30 PM		01:10–02:00 PM	2.00-2:50 P.M	2:50-3:40 P.M.	3.40-4.30 PM
Mon	Biochem Lab B-3 (TSP) CA Lab B-4 (PR)					POC-I(ChM)	Biochem (TSP)	Tutorial	HAP-II(GS)
Tue	Biochem Lab B-4 (TSP) CA Lab B-3(PR)					EVS(KSR)	HAP-II(GS)	Library	Tutorial
Wed	HAP Lab B-3 (GS) POC-1 Lab B-4 (ChM)					EVS (KSR)	Yoga	Remedial Class	Library
Thu	HAP Lab B4 (GS) POC-1 Lab B-3 (ChM)					Patho(PG)	Yoga	Remedial Class	Tutorial
Fri	Yoga	CA (PR)	Biochem(TSP)	Patho(PG)		POC-I(ChM)	EVS (KSR)	Yoga	Tutorial
Sat	HAP-II(GS)	CA (PR)	Biochem(TSP)	Patho(PG)		Sports	POC-I (ChM)	CA (PR)	Sports

POC-I: Pharmaceutical Organic Chemistry-I- (ChM)- Dr.Ch.Mahesh, Patho: Pathophysiology- (PG)-Dr. P.Girija, HAP-II: Human Anatomy and Physiology-II- (GS)- Dr.G.Supriya, Biochem: Biochemistry-(TSP)- Mrs.T.Sushma Preethi, CA: Computer Applications in Pharmacy- (PR)- Mrs. P.Ramadevi, EVS: Environmental sciences- (KSR)- Dr.K.Srinivas Reddy.

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course.

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VAAGDEVI COLLEGE OF PHARMACY

RAMNAGAR, HANAMKONDA

B.Pharmacy III Sem Section-A 2023-24

Day/ Time	I	II	III	IV		Practical V	VI	VII	VIII
	09:10–10:00 AM	10:00–10:50 AM	10:50-11:40 AM	11:40–12:30 PM		01:10-04:30 PM			
Mon	POC-II (MS)	PP-I (VS)	Library	Tutorial		P'MicrobiologyLab B-1 (KR) P'Eng. Lab B-2 (TR)			
Tue	POC-II (MS)	PP-I (VS)	Remedial class	Tutorial		P'MicrobiologyLab B-2 (KR) P'Eng. Lab B-1 (TR)			
Wed	POC-II (MS)	P' Eng. (TR)	Tutorial PP-I	P'MB (KR)	LUNCH: 12:30to01:10PM	POC-II Lab B-2 (MS) PP-I Lab B-1 (VS)			
Thu	Yoga	P' Eng. (TR)	Tutorial POC-II	P'MB (KR)		POC-II Lab B-1 (MS) PP-I Lab B-2 (VS)			
Fri	Yoga	P' Eng. (TR)	Tutorial P'MB	Library		Tutorial	Remedial class		
Sat	PP-I (VS)	P'MB (KR)	Tutorial P' Eng.	Tutorial		Sports			

POC-II: Pharmaceutical Organic Chemistry-(MS)-Ms.M.Shruthi, P'ENG: Pharmaceutical Engineering-(TR)-Mrs.T.Rajani, PP-I: Physical Pharmaceutics-I -(VS)-Mrs.V.Srilekha PMB: Pharmaceutical Microbiology-(KR)-Mrs.K.Ragini.

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course.

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B.Pharmacy III Sem Section-B 2023-24

Day/ Time	I	II	III	IV		V	VI	VII	VIII
	09:10–10:00 AM	10:00–10:50 AM	10:50-11:40 AM	11:40–12:30 PM		01:10–02:00 PM	2.00-2:50 PM	2.50 - 3:40 PM	3.40-4.30 PM
Mon	P' Microbiology Lab B-3(TK) P' Eng. Lab B-4 (DS)				LUNCH: 12:30 to 01:10PM	PP-I (VS)	POC-II (Ch.M)	Library	Tutorial
Tue	P' Microbiology LabB-4 (TK) P' Eng. Lab B-3 (DS)					PP-I (VS)	Tutorial	Tutorial	Remedial Class
Wed	PP-I Lab B-3 (VS) POC-II Lab B-4 (Ch.M)					PMB (TK)	P'.Eng. (DS)	Tutorial PP-I	Tutorial
Thu	PP-I Lab B-4 (VS) POC-II Lab B-3(Ch.M)					PMB (TK)	P'.Eng. (DS)	Tutorial POC-II	Tutorial
Fri	POC-II (Ch.M)	Yoga	PP-I (VS)	Remedial class		PMB (TK)	Tutorial	Tutorial P'.Eng.	Tutorial
Sat	POC-II (Ch.M)	Yoga	Tutorial PMB	Library		P'.Eng. (DS)	Sports	Sports	Sports

POC-II: Pharmaceutical Organic Chemistry-II-(Ch.M)-Dr.Ch.Mahesh, PP-I: Physical Pharmaceutics-I-(AMS)-(VS)-Mrs.V.Swetha, PMB: Pharmaceutical Microbiology-(TK)- Mrs.T.Keerthi , P'.Eng: Pharmaceutical Engineering –(DS)-Mrs.D.Sushma.

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course.

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RAMNAGAR, HANAMKONDA

B.Pharmacy IV Sem Section-A 2023-24

Day/ Time	I	II	III	IV		Practical V VI VII VIII
	09:10–10:00 AM	10:00– 10:50 AM	10:50-11:40 AM	11:40–12:30 PM		01:10PM - 4:30 PM
Mon	POC-III(LM)	PP-II (SS)	Tutorial	P' Cognosy-I (BKV)		P' Cology Lab B-1 (MSL) P'Cognosy Lab B-2 (BKV)
Tue	POC-III (LM)	Library	PP-II (SS)	P' Cognosy-I (BKV)		P' Cology Lab B-2 (MSL) P' Cognosy Lab B-1 (BKV)
Wed	POC-III (LM)	P' Cology (MSL)	Tutorial	Yoga		MC-I Lab B-2 (MS) PP-II Lab B-1 (SS)
Thu	MC-I (MS)	Remedial Class	PP-II (SS)	Tutorial		MC-I Lab B-1 (MS) PP –II Lab B-2 (SS)
Fri	MC-I (MS)	Yoga	P' Cology (MSL)	P' Cognosy-I (BKV)		Sports
Sat	MC-I (MS)	Tutorial	Remedial Class	P' Cology (MSL)		Sports

LUNCH: 12:30 to 01:10 PM

PP-II: Physical Pharmaceutics-II-(SS)-Dr.S.Sireesha, P' Cology-I:Pharmacology-I-(MSL)- Mrs.M.Sumalatha, P' Cognosy: Pharmacognosy and Phytochemistry-I-(BKV) -Mrs.B.Krishnaveni, POC-III: Pharmaceutical Organic Chemistry-III-(LM)- Mrs.L.Maneesha, MC-I: Medicinal Chemistry-I-(MS)- Ms.M.Shruthi

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course.

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VAAGDEVI COLLEGE OF PHARMACY

RAMNAGAR, HANAMKONDA

B.Pharmacy IV Sem Section B 2023-24

Day/ Time	I	II	III	IV	LUNCH: 12:30to01:10PM	V	VI	VII	VIII
	09:10– 10:00 AM	10:00– 10:50 AM	10:50-11:40 AM	11:40–12:30 PM		01:10–02:00 PM	2.00-2:50 PM	2:50-3:40 PM	3.40 – 4.30 PM
Mon	MC-1 Lab B-3 (LM) PP Lab B-4 (VS)					P' Cology-I (DM)	PP-II (VS)	Tutorial	Tutorial
Tue	MC-1 Lab B-4 (LM) PP Lab B-3 (VS)					P' Cology-I (DM)	P'Cognosy-I (CSR)	Remedial Class	Tutorial
Wed	P' Cognosy-I Lab B-3 (BKV) P' Cology Lab B-4 (DM)					P' Cology-I (DM)	Library	Tutorial	MC-1 (DKS)
Thu	P' Cognosy-I Lab B-4 (BKV) P' Cology Lab B-3 (DM)					PP-II (VS)	MC-1 (DKS)	Tutorial	POC-III (Ch.M)
Fri	Tutorial	P' Cognosy-I (CSR)	Yoga	Library		Tutorial	Tutorial	MC-1 (DKS)	POC-III (Ch.M)
Sat	PP-II (VS)	Tutorial	P' Cognosy-I (CSR)	Remedial Class		Yoga	POC-III (Ch.M)	Sports	Sports

PP-II: Physical Pharmaceutics-II-(VS)- Mrs.V.Srilekha, P' Cology-I:Pharmacology-I- (DM)-Mrs.D.Mounika, P' Cognosy: Pharmacognosy and Phytochemistry-I-(CSR)- Dr.C.Srinivas Reddy, BKV:Mrs.B.Krishnaveni (Pr), POC-III: Pharmaceutical Organic Chemistry-III-(ChM)- Dr.Ch.Mahesh, MC-I: Medicinal Chemistry-I-(DKS)- Dr.D.Kumara Swamy (Th), LM: L.Maneesha (Pr)

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course.

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VAAGDEVI COLLEGE OF PHARMACY

RAMNAGAR, HANAMKONDA

B.Pharmacy V Sem Section-A 2023-24

Day/ Time	I	II	III	IV	LUNCH: 12:30to01:10 PM	V	VI	VII	VIII
	09:10–10:00 AM	10:00–10:50 AM	10:50-11:40 AM	11:40–12:30 PM		01:10–02:00PM	2.00-2:50PM	2:50-3:40 PM	3:40-4.30PM
Mon	IP-I Lab B-1 (TR) P' Cology-II B-2 (ERR)					P'Cology-II (ERR)	Tutorial MC-II	IP-I (TR)	Library
Tue	IP-I Lab B-2 (TR) P' Cology-II B-1 (ERR)					P' Cology-II (ERR)	Yoga	Tutorial P' Cognosy-II	IP-I (TR)
Wed	P' Cognosy –II Batch-1(BKV)					P' Cology-II (ERR)	P' Juris (LSM)	Tutorial IP-I	Tutorial
Thu	P' Cognosy-II B-2 (BKV)					P' Cognosy-II (CSR)	Library	Tutorial P'Cology-II	Tutorial
Fri	MC-II (ChM)	Tutorial P' Juris	P' Juris (LSM)	Remedial class		P' Cognosy-II (CSR)	Tutorial	Tutorial	MC-II (ChM)
Sat	IP-I (TR)	Yoga	P' Juris (LSM)	Remedial class		P' Cognosy-II (CSR)	MC-II (ChM)	Sports	Sports

P' Juris: Pharmaceutical Jurisprudence-(LSM)- Mrs.L.Smitha, P' Cology-II: Pharmacology- (ERR)-Mr.E.Rajeev Reddy, MC-II: Medicinal Chemistry-II-(ChM)-Dr.Ch.Mahesh, IP-I: Industrial Pharmacy-I-(TR)-Mrs.T.Rajani, P' Cognosy-II: Pharma cognosy and Phytochemistry-II- (CSR)-Dr. Challa Srinivas Reddy(Th), (GS)-Mrs.B.Krishnaveni (Pr),

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course.

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VAAGDEVI COLLEGE OF PHARMACY

RAMNAGAR, HANAMKONDA

B.Pharmacy V Sem Section-B 2023-24

Day/ Time	I	II	III	IV		Practical V VI VII VIII
	09:10–10:00 AM	10:00–10:50 AM	10:50-11:40 AM	11:40–12:30PM		01:10PM - 4:30 PM
Mon	MC-II (Ch.M)	P' Juris (DS)	Tutorial P' Juris	P'Cognosy-II (BKV)		P'Cognosy-II Lab Batch-3 (BKV) P'Cology-II Lab Batch-4 (MSL)
Tue	MC-II (Ch.M)	Tutorial P'Cognosy-II	P' Cology-II (MSL)	P' Juris (DS)		P' Cognosy-II Lab Batch-4 (BKV) P' Cology-II Lab Batch-3 (MSL)
Wed	MC-II (Ch.M)	IP-I (VR)	Tutorial P' Cology-II	Yoga		IP-I Lab Batch-4 (VR)
Thu	IP-I (VR)	P' Cology-II (MSL)	Remedial Class	Tutorial IP-I		IP-I Lab Batch-3 (VR)
Fri	IP-I (VR)	P' Cognosy-II (BKV)	P' Cology-II (MSL)	Tutorial MC-II		Remedial class
Sat	Tutorial	P' Juris (DS)	P' Cognosy-II (BKV)	Library		Sports

LUNCH: 12:30 to 01:10 PM

P' Juris: Pharmaceutical Jurisprudence-(DS)- Mrs.D.Sushma, Dr.Ch.Mahesh, IP-I: Industrial Pharmacy-I-(VR)-Ms.V.Rashmitha, P' Cology-II: Pharmacology-(MSL)-Mrs.M.Sumalatha, MC-II:Medicinal Chemistry-II-(Ch.M)- P' Cognosy: Pharma cognosy and Phytochemistry-II- (BKV)-Mrs.B.Krishnaveni.

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course.

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VAAGDEVI COLLEGE OF PHARMACY

RAMNAGAR, HANAMKONDA

B.Pharmacy VI Sem Sec A 2023-24

Day/ Time	I	II	III	IV		Practical
	09:10– 10:00 AM	10:00– 10:50 AM	10:50-11:40 AM	11:40–12:30 PM		01:10PM - 4:30 PM
Mon	P' Biotech (MM)	HDT (VR)	Tutorial	BPPK (VS)	LUNCH: 12:30 to 01:10PM	MC-III Lab Batch-1 (MS) HDT Lab Batch-2 (VR)
Tue	P' Biotech (MM)	HDT (VR)	Tutorial	BPPK (VS)		MC-III Lab Batch-2 (MS) HDT Lab Batch-1 (VR)
Wed	P' Biotech (MM)	HDT (VR)	Tutorial	BPPK (VS)		P' Cology Lab Batch-1 (ERR)
Thu	Tutorial	P' Cology (ERR)	QA (TR)	MC-III (MS)		P' Cology Lab Batch-2 (ERR)
Fri	Tutorial	P' Cology (ERR)	QA (TR)	MC-III (MS)		Library
Sat	Tutorial	P' Cology (ERR)	QA (TR)	MC-III (MS)		Sports

QA: Quality Assurance-(TR)- Mrs.T.Rajani, HDT: Herbal Drug Technology-(VR)- Ms.V.Rashmitha, BPPK: Biopharmaceutics and Pharmacokinetics- (VS)-Mrs.V.Srilekha, P' Biotech: Pharmaceutical Biotechnology(MM)- Mrs.M.Mounika, P' Cology: Pharmacology-(ERR) –Mr.E.Rajeev Reddy, MC-III: Medicinal Chemistry-III-(MS) –Ms.M.Shruthy.

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course.

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RAMNAGAR, HANAMKONDA

B.Pharmacy VI Sem Section B 2023-24

Day/ Time	I	II	III	IV	LUNCH: 12:30to01:10PM	V	VI	VII	VIII
	09:10– 10:00 AM	10:00– 10:50 AM	10:50-11:40 AM	11:40–12:30 PM		01:10–02:00 PM	2.00-2:50 PM	2:50-3:40 PM	3.40 – 4.30 PM
Mon	MC-III Lab Batch-1 (LM) HDT Lab Batch-2 (VR)					P' Biotech (MM)	HDT (VR)	BPPK (VS)	Tutorial
Tue	MC-III Lab Batch-2 (LM) HDT Lab Batch-I (VR)					BPPK (VS)	P' Biotech (MM)	Remedial Class	HDT (VR)
Wed	P' Cology Lab Batch-1 (ERR)					MC-III (LM)	Library	Tutorial	QA (TR)
Thu	P' Cology Lab Batch-2 (ERR)					MC-III (LM)	QA (TR)	Tutorial	Tutorial
Fri	P' Cology (ERR)	P' Biotech (MM)	Yoga	Library		HDT (VR)	Tutorial	BPPK (AA)	QA (TR)
Sat	BPPK (VS)	P' Cology (ERR)	MC-III (LM)	Remedial Class		Yoga	P' Cology (ERR)	Sports	Sports

QA: Quality Assurance-(TR)- Mrs.T.Rajani, HDT: Herbal Drug Technology-(VR)- Ms.V.Rashmitha, BPPK: Biopharmaceutics and Pharmacokinetics- (VS)-Mrs.V.Srilekha, P' Biotech: Pharmaceutical Biotechnology(MM)- Mrs.M.Mounika, P' Cology: Pharmacology-(ERR) –Mr.E.Rajeev Reddy, MC-III: Medicinal Chemistry-III-(LM)-Mrs-L.Maneesha.

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course.

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RAMNAGAR, HANAMKONDA

B.Pharmacy VII Sem Sec A 2023-24

Day/ Time	I	II	III	IV	LUNCH: 12:30to01:10PM	Practical V VI VII VIII
	09:10–10:00AM	10:00–10:50 AM	10:50-11:40 AM	11:40–12:30 PM		01:10PM – 4.30 PM
Mon	Yoga	IP-II (SS)	Tutorial	IMA (DKS)		Practice School B-1 & 2
Tue	IMA (DKS)	IP-II (SS)	Tutorial	Yoga		Practice School B-1 & 2
Wed	Remedial Class	IP-II (SS)	Tutorial	IMA (DKS)		Practice School B-1 & 2
Thu	Tutorial	NDDS (KN)	PP (GS)	Remedial class		IMA Lab B-1 (DKS) Practice School B-2
Fri	PP (GS)	NDDS (KN)	Library	Remedial class		IMA Lab B-2 (DKS) Practice School B-1
Sat	PP (GS)	NDDS (KN)	Sports			Competitive Exam preparation (2.00PM to 3.00PM)

IMA: Insrumental Methods of Analysis- (DKS)-Dr.D.Kumara Swamy, IP-II: Industrial Pharmacy-II-(SS)-Mrs.S.Sirisha,

PP: Pharmacy Practice-(GS)-Mrs.G.Swapna, NDDS: Novel Drug Delivery System-(BV)-Mrs.K.Nandini.

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course.

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RAMNAGAR, HANAMKONDA

B.Pharmacy VII Sem Sec B 2023-24

Day/ Time	I	II	III	IV		Practical V VI VII VIII
	09:10–10:00AM	10:00–10:50 AM	10:50-11:40 AM	11:40–12:30 PM		01:10PM – 4.30 PM
Mon	Yoga	IP-II (AM)	Tutorial	IMA (CHM)		IMA Lab B-1 (CHM) Practice School B- 2
Tue	IMA (CHM)	IP-II (AM)	NDDS Tutorial	Yoga		IMA Lab B-2 (CHM) Practice School B- 1
Wed	IMA (CHM)	IP-II (AM)	Tutorial	Library		Practice School B-1 & 2
Thu	Tutorial	NDDS (MSV)	PP (BB)	Remedial class		Practice School B-1&2
Fr:	PP (BB)	NDDS (MSV)	Remedial Class	Remedial class		Practice School B-1 &2
Sa:	PP (BB)	NDDS (MSV)	Sports			Competitive Exam preparation (2.00PM to 3.00PM)

LUNCH: 12:30to01:10PM

IMA: Insrumental Methods of Analysis- (CHM)-Dr.Ch.Mahesh, IP-II: Industrial Pharmacy-II-(AM)-Dr.A.Madhusudhan,

PP: Pharmacy Practice-(BB)-Mrs.B.Bhavani, NDDS: Novel Drug Delivery System-(MSV)-Mrs.M.Shravanthi.

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course.

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RAMNAGAR, HANAMKONDA

B.Pharmacy VIII Sem, Sec A 2023-24

Day/ Time	I	II	III	IV	LUNCH: 12:30 to 01:10 PM	V VI VII VIII
	09:10–10:00 AM	10:00–10:50 AM	10:50-11:40 AM	11:40–12:30PM		01:10PM – 4:30 PM
Mon	BRM (PG)	Library	Tutorial	E-2 (SP)		Project Work
Tue	E-1 (PK)	Tutorial	BRM (PG)	E-2 (SP)		Project Work
Wed	BRM (PG)	Yoga	Tutorial BRM	Library		Project Work
Thu	SPP (BSB)	Yoga	E-1 (PK)	Remedial Class		Tutorial
Fri	SPP (BSB)	E-2 (SP)	Tutorial	Remedial Class		Tutorial
Sat	SPP(BSB)	Tutorial	E-1 (PK)	Tutorial		Sports

BRM: Biostatistics and Research Methodology-(PG)- Dr.P.Gopinath, SPP: Social and Preventive Pharmacy-(BSB)-Dr.B.Sharavana Bhava, E-1: Experimental Pharmacology-(PK)- Mrs.P.Kalyani, E-2: Quality Control and Standardization of Herbals-(SP) -Dr.S.Pavani.

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course.

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RAMNAGAR, HANAMKONDA

B.Pharmacy VIII Sem Section B 2023-24

Day/ Time	I	II	III	IV	LUNCH: 12:30to01:10PM	V	VI	VII	VIII
	09:10– 10:00 AM	10:00– 10:50 AM	10:50-11:40 AM	11:40–12:30 PM		01:10–02:00 PM	2.00-2:50 PM	2:50-3:40 PM	3.40 – 4.30 PM
Mon	Project Work					BRM (PG)	E-1 (PK)	Tutorial	Tutorial
Tue	Project Work					BRM (PG)	E-2 (SS)	Remedial Class	Tutorial
Wed	Project Work					BRM (PG)	Library	Tutorial	Tutorial
Thu	Tutorial					SPP (BSB)	Tutorial	Tutorial	Tutorial
Fri	E-1 (PK)	E-2 (SS)	Yoga	Library		SPP (BSB)	Tutorial	Tutorial	Tutorial
Sat	E-1 (PK)	E-2 (SS)	SPP (BSB)	Remedial Class		Yoga	Tutorial	Sports	Sports

BRM: Biostatistics and Research Methodology-(PG)- Dr.P.Gopinath, SPP: Social and Preventive Pharmacy-(BSB)-Dr.B.Sharavana Bhava, E-1: Experimental Pharmacology-(PK)- Mrs.P.Kalyani, E-2: Quality Control and Standardization of Herbals-(SS) –Dr.S.Sireesha

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course.

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VAAGDEVI COLLEGE OF PHARMACY

RAMNAGAR, HANAMKONDA

Pharm. D I Year 2023-24

Day/ Time	I	II	III	IV		Practical V	VI	VII
	09:10–10:00 AM	10:00–10:50 AM	10:50-11:40 AM	11:40–12:30 PM		02:00–02:50 PM	2.50-3:40 PM	3:40-4:30 PM
Mon	P' Ceutics (TR)	Tutorial POC	HAP (MM)	Med. Biochem (LM)		HAP Lab (MM)		
Tue	HAP (MM)	P' Ceutics (TR)	Tutorial PIC	Med. Biochem (LM)		Biology Lab (KSR)		
Wed	HAP (MM)	Med. Biochem (LM)	Tutorial P' Ceutics	Library		Med. Biochemistry Lab (LM)		
Thu	POC (MS)	Tutorial M. Biochem	Remedial Class	PIC (MSL)		POC Lab (MS)		
Fri	Tutorial HAP	RM (SA)	POC (MS)	RB (KSR)		PIC Lab (MSL)		
Sat	POC (MS)	RM (SA)	Tutorial RM/RB	PIC (MSL)		P' Ceutics Lab (TR)		

LUNCH:12:30to01:30PM

P'Ceutics: Pharmaceutics-(TR)-Mrs.T.Rajani, HAP: Human Anatomy and Physiology-(MM)-Mrs.M.Madhavi, Med.Biochem: Medicinal Biochemistry-(LM)-Mrs.L.Maneesha, POC: Pharmaceutical Organic Chemistry-(MS)-Ms.M..Shruthi, PIC: Pharmaceutical Inorganic Chemistry-(MSL)-Mrs.M.Sumalatha, RM: Remedial Mathematics-(SA)-Mrs.Sameena Afreen, RB: Remedial Biology-(KSR)- Dr.K.Srinivas Reddy.

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course.

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VAAGDEVI COLLEGE OF PHARMACY

RAMNAGAR, HANAMKONDA

Pharm. D II Year 2023-24

Day/ Time	I	II	III	IV		Practical V	VI	VII
	09:10–10:00 AM	10:00–10:50 AM	10:50-11:40 AM	11:40–12:30 PM		02:00–02:50 PM	2.50-3:40 PM	3:40-4:30 PM
Mon	Pathophysiology (ABG)	PMB (PGM)	Tutorial P' Cology-I	Yoga		PMB Lab (PGM)		
Tue	Pathophysiology (ABG)	Ward rounds				Case Discussions @ MGM Hospital		
Wed	P' Cognosy (KSR)	P' Cology-I (KSV)	Tutorial Pathophysiology	Tutorial PT-I		P' Cognosy Lab (KSR)		
Thu	P' Cology-I (KSV)	Tutorial P' Cognosy	Comm. Pharmacy (GS)	PMB (PGM)		Pathophysiology (ABG)	P' Cognosy (KSR)	PT-I (SN)
Fri	P' Cology-I (KSV)	PMB (PGM)	Tutorial Comm. Pharmacy	Tutorial		PT-I (SN)	Yoga	Library
Sat	Comm. Pharmacy (GS)	P' Cognosy (KSR)	Remedial Class	Tutorial PMB		Case Presentations		PT-I (SN)

LUNCH: 12:30to01:30PM

Pathophysiology-(ABG)-Dr.A.Bhagya sri, P'Cognosy: Pharmacognosy and Phytopharmaceuticals-(KSR)-Dr.K.Srinivas Reddy, P'Cology-I: Pharmacology-I-(KSV)-Dr.K.Sai Vamshi, PMB: Pharmaceutical Microbiology-(PGM)-Mr.P.Goutham, Comm.Pharmacy: Community Pharmacy-(GS)-Dr.G.Supriya, PT-I: Pharmacotherapeutics-I-(SN)-Dr.Safiya Naseer.

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course.

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VAAGDEVI COLLEGE OF PHARMACY

RAMNAGAR, HANAMKONDA

Pharm. D III year 2023-24

Day/ Time	I	II	III	IV		V	VI	VII
	09:10-10:00AM	10:00-10:50AM	10:50-11:40AM	11:40–12:30PM		02:00–02:50 PM	2.50-3:40PM	3:40-4:30PM
Mon	PT-II (AM)	Ward Rounds @ MGM				Tutorial P' Cology-II	PT-II (AM)	Tutorial PT-II
Tue	P' Cology-II (BV)	P' Juris (PG)	Tutorial	PF (TSP)		P' Cology-II Lab (BV)		
Wed	Yoga	Ward Rounds @ MGM				Tutorial P' Analysis	PT-II (AM)	Library
Thu	P' Analysis (LM)	MC (MS)	P' Cology-II (BV)	PF (TSP)		MC Lab (MS)		
Fri	P' Analysis (LM)	MC (MS)	PT-II (AM)	P' Juris (PG)		PF Lab (TSP)		
Sat	P' Cology-II (BV)	MC (MS)	P' Analysis (LM)	PT-II (AM)		P' Analysis Lab (LM)		

LUNCH: 12:30to01:30PM

P'Cology-II: Pharmacology-II-(BV)-Mr.B.Venkatesh, P'Analysis: Pharmaceutical Analsis-(LM)-Mrs.L.Maneesha, MC: Medicinal Chemisty-(MS)-Ms.M.Shruthy, P' Juris: Pharmaceutical Jurisprudence-(PG)-Mr.P.Goutham, PF: Pharmaceutical Formulations-(TSP)-Mrs.T.Sushma Preethi, PT-II: Pharmacotherapeutics-II-(AM)-Dr.A.Makarandh

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course.

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VAAGDEVI COLLEGE OF PHARMACY

RAMNAGAR, HANAMKONDA

Pharm.D IV Year 2023-24

Day/ Time	I	II	III	IV	LUNCH: 12:30 to 02:00 PM	V	VI	VII
	09:10-10:00AM	10:0010:50AM	10:50-11:40AM	11:40–12:30PM		02:00–02:50PM	2.50-3:40PM	3:40-4:30PM
Mon	BPPK (BV)	Tutorial BS&RM	BS&RM (DG)	CT (GA)		BPPK Lab (BV)		
Tue	BPPK (BV)	Tutorial CP	BS&RM (DG)	CT (GA)		HP Lab (GS)		
Wed	BPPK (BV)	Remedial Class	Tutorial BPPK	Library		Case Presentations		
Thu	PT-III (SN)	Ward rounds				HP (AM)	CP (AMS)	Library
Fri	PT-III (SN)	Ward rounds				HP (AM)	CP (AMS)	Tutorial HP
Sat	CP (AMS)	Ward rounds				CP Lab (BSB)		

FT-III: Pharmacotherapeutics-III-(SN)-Dr.Safiya Naseer, HP: Hospital Pharmacy Therory-(AM)-Dr.A.Makandh, HP: Hospital Pharmacy Practical-(GS)-Dr.G.Supriya, CP: Clinical Pharmacy Practical (BSB)-Dr. B.S. Sharvana bhava, CP: Clinical Pharmacy Theory-(AMS)-Dr.A.Madhu Sudhan, CT: Clinical Toxicology-(GA)-Dr.G.Anusha, BPPK: Biopharmaceutics & Pharmacokinetics-(BV)-Mr.B.Venkatesh BS&RM: Biostatistics & Research Methodology-(DG)-Dr.D.Gopinath

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course. PRINCIPAL

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RAMNAGAR, HANAMKONDA

Pharm. D V year 2023-24

Day/ Time	I	II	III	IV		V	VI	VII
	09:10–10:00AM	10:0010:50AM	10:50-11:40 AM	11:40–12:30PM		02:00-02:50PM	2.50-3:40PM	3:40-4:30PM
Mon	CR (BSB)	Clerkship			LUNCH: 12:30to01:30PM	CPK.TDM (GA)	Project Work	
Tue	CR (BSB)	Clerkship				CPK.TDM (GA)	Project Work	
Wed	CR (BSB)	Clerkship				Project Work		
Thu	PEPE (VS)	Clerkship				Project Work		
Fri	PEPE (VS)	Clerkship				Project Work		
Sat	PEPE (VS)	Clerkship				Project Work		

CR: Clinical Research-(BSB)-Dr.B.S.Sharvana Bhava, PEPE: Pharmacoepidemiology and Pharmacoeconomics-(VS)-Dr.V.Snehapriya, CPK.TDM: Clinical Pharmacokinetics & Pharmacotherapeutic-(GA)-Dr.G.Anusha

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course.

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VAAGDEVI COLLEGE OF PHARMACY

RAMNAGAR, HANAMKONDA

M.Pharmacy Pharmacetical Analysis I SEM 2023-24

Day/ Time	I	II	III	IV		Practical V	VI	VII
	09:10–10:00AM	10:00–10:50AM	10:50-11:40AM	11:40–12:30PM		02:00–02:50PM	2.50-3:40PM	3:40-4:30PM
Mcn	APAT (DKS)	Yoga	BS (KSR)	PA-I (MS)		APAT Lab (DKS)		
Tue	Tutorial	Yoga	BS (KSR)	PA-I (MS)		APAT Lab (DKS)		
Wed	APAT (DKS)	Tutorial APAT	QC (ChM)	PA-I (MS)		APAT Lab (DKS)		
Thu	Journal club	Tutorial APAT	BS (KSR)	APAT (DKS)		PA-I Lab (MS)		
Fri	Journal club	QC (ChM)	Seminar			PA-I Lab (MS)		
Sat	Library	QC (ChM)	Seminar			PA-I Lab (MS)		

LUNCH: 12:30to01:30PM

APAT: Modern Pharmaceutical Analytical Techniques-(DKS)-Dr.D.Kumara Swamy, PA-I: Pharmaceutical Analysis –I - (MS)-Ms.M.Shruthi,

QC: Quality control of pharmaceutical dosage forms- (ChM)-Dr.Ch.Mahesh BS : Biological Standardization -(KSR)-Dr.K.Srinivas Reddy.

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RAMNAGAR, HANAMKONDA

M. Pharm Analysis II SEM 2023-24

Day/ Time	IHour	IIHour	IIIHour	IVHour		Practical		
	09:10–10:00AM	10:00–10:50AM	10:50-11:40. AM	11:40–12:30PM		02:00–02:50 PM	2.50-3:40 P.M	3:40-4:30 P.M.
Mon	AMDV (CHM)	Tutorial PA-II	QA (DKS)	Journal Club		AMDV Lab (CHS)		
Tue	Tutorial PA-II	AMDV (CHM)	QA (DKS)	Tutorial RA		AMDV Lab (CHS)		
Wed	AMDV (CHM)	Tutorial AMDV	QA (DKS)	Tutorial RA		AMDV Lab (CHS)		
Thu	PA-II (MS)	Tutorial AMDV	RA (SP)	Seminar		PA-II Lab (MS)		
Fri	PA-II (MS)	Tutorial QA	RA (SP)	Seminar		PA-II Lab (MS)		
Sat	PA-II (MS)	Tutorial QA	RA (SP)	Seminar		PA-II Lab (MS)		

LUNCH: 12:30to01:30PM

AMDV:Analytical method development and validation-(ChM)- Dr.Ch.Mahesh, PA-II: Pharmaceutical Analysis –II-(MS) Ms.M.Shruthy, QA: Quality assurance-(DKS) Dr.D.Kumara Swamy, RA: Regulatory affairs-(SP)- Dr.S.Pavani

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VAAGDEVI COLLEGE OF PHARMACY

RAMNAGAR, HANAMKONDA

M.Pharmacy Pharmacology I-SEM 2023-24

Day/ Time	I	II	III	IV		Practical V	VI	VII
	09:10–10:00AM	10:0010:50AM	10:50-11:40AM	11:40–12:30PM		02:00–02:50PM	2.50-3:40PM	3:40-4:30PM
Mon	AP-I (PG)	Tutorial APE-I	APE-I (MM)	Journal Club		Advanced Pharmacology Lab (PG)		
Tue	AP-I (PG)	Tutorial APE-I	APE-I (MM)	Tutorial PPDM		Advanced Pharmacology Lab (PG)		
Wed	AP-I (PG)	Tutorial AP-I	APE-I (MM)	Tutorial PPDM		Advanced Pharmacology Lab (PG)		
Thu	AP-II (EVR)	Tutorial AP-I	PPDM (BN)	Seminar		PPDM Lab (BN)		
Fri	AP-II (EVR)	Tutorial AP-II	PPDM (BN)	Seminar		PPDM Lab (BN)		
Sat	AP-II (EVR)	Tutorial AP-II	PPDM (BN)	Library		PPDM Lab (BN)		

LUNCH: 12:30to01:30PM

AP-II: Advanced Pharmacology-II-(EVR)-Dr.E.Venkateshwarlu, AP-I: Advanced Pharmacology-I-(PG)-Dr.P.Girija Advances in Preclinical Evaluation-I-APE-I -(MM)-Dr.M.Madhavi, PPDM : Pharmacokinetics, Pharmacodynamics & Drug Metabolism-(BN) –Mrs.B.Neeraja

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course.

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VAAGDEVI COLLEGE OF PHARMACY

RAMNAGAR, HANAMKONDA

M. Pharm Cology II-SEM 2023-24

Day/ Time	IHour	IIHour	IIIHour	IVHour		Practical		
	09:10–10:00AM	10:00–10:50AM	10:50-11:40. AM	11:40–12:30PM		02:00–02:50 PM	2.50-3:40 P.M	3:40-4:30 P.M.
Mon	CPT (BSB)	Tutorial APE-II	CR (PG)	Journal Club	LUNCH: 12:30to01:30PM	CPT Lab (BSB)		
Tue	CPT (BSB)	Tutorial APE-II	CR (PG)	Tutorial MBPBDDD		CPT Lab (BSB)		
Wed	CPT (BSB)	Tutorial CPT	CR (PG)	Tutorial MBPBDDD		CPT Lab (BSB)		
Thu	APE-II (EVR)	Tutorial CPT	MBPBDDD (MM)	Seminar		APE Lab (EVR)		
Fri	APE-II (EVR)	Tutorial CR	MBPBDDD (MM)	Seminar		APE Lab (EVR)		
Sat	APE-II (EVR)	Tutorial CR	MBPBDDD (MM)	Seminar		APE Lab (EVR)		

CPT: Clinical Pharmacology and Toxicology-(BSB)-Dr.B.S.Sharavana Bhava, CR:Clinical Research-(PG)-Dr.P.Girija, APE-II: Advances in Preclinical Evaluation-II-(EVR)-Dr.E.Venkateshwarlu, MBPBDDD: Molecular & Biochemical Pharmacology Basis of Drug Discovery & Development -(MM)-Mrs.M.Madhavi

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VAAGDEVI COLLEGE OF PHARMACY

RAMNAGAR, HANAMKONDA

M.Pharmacy Pharmaceutics I Sem 2023-24

Day/ Time	I	II	III	IV		Practical V	VI	VII
	09:10–10:00AM	10:00–10:50AM	10:50-11:40AM	11:40–12:30PM		02:00–02:50PM	2.50-3:40PM	3:40-4:30PM
Mon	Tutorial QA	BPPK (YSK)	PP (SP)	Journal Club		BPPK Lab (YSK)		
Tue	BPPK (YSK)	Tutorial QA	PP (SP)	Tutorial QA		BPPK Lab (YSK)		
Wed	BPPK (YSK)	Tutorial BPPK	PP (SP)	Tutorial QA		BPPK Lab (YSK)		
Thu	PFT (SS)	Tutorial BPPK	QA (AM)	Seminar		PFT&PP Lab (SP)		
Fri	PFT (SS)	Tutorial PP	QA (AM)	Seminar		PFT&PP Lab (SP)		
Sat	PFT (SS)	Tutorial PP	QA (AM)	Library		PFT&PP Lab (SP)		

LUNCH: 12:30to01:30PM

BPPK: Bio Pharmaceutics & Pharmacokinetics-(YSK)-Dr.Y.Shravan Kumar, PFT: Pharmaceutical Formulation Technology-(SS)-Dr.S.Sireesha, PP: Physical Pharmaceutics-(SP)-Dr.S.Pavani, QA: Quality Assurance-(AM)-Dr.A.Madhusudhan

Note: 4.30 PM – 5.30 PM (Monday -Saturday) Value added Course. Enrolled students attend your Value added Course.

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VAAGDEVI COLLEGE OF PHARMACY

RAMNAGAR, HANAMKONDA

M. Pharm Pharmaceutics II Sem 2023-24

Day/ Time	IHour	IIHour	IIIHour	IVHour		Practical		
	09:10–10:00AM	10:00–10:50AM	10:50-11:40. AM	11:40–12:30PM		02:00–02:50 PM	2.50-3:40 P.M	3:40-4:30 P.M.
Mon	Tutorial RA	NDDS-I (YSK)	P'Equip (RLK)	Journal Club		NDDS-I Lab (YSK)		
Tue	NDDS-I (YSK)	Tutorial RA	P'Equip (RLK)	Tutorial NDDS-II		NDDS-I Lab (YSK)		
Wed	NDDS-I (YSK)	Tutorial P'Equip	P'Equip (RLK)	Tutorial NDDS-II		NDDS-I Lab (YSK)		
Thu	NDDS-II (SP)	Tutorial P'Equip	RA (SS)	Seminar		NDDS-II & P'Equip Lab (SP)		
Fri	NDDS-II (SP)	Tutorial NDDS-I	RA (SS)	Seminar		NDDS-II & P'Equip Lab (SP)		
Sat	NDDS-II (SP)	Tutorial NDDS-I	RA (SS)	Seminar		NDDS-II & P'Equip Lab (SP)		

LUNCH: 12:30to01:30PM

NDDS-I: Novel Drug Delivery System-I-(YSK) -Dr.Y.Shravan Kumar, NDDS-II: Novel Drug Delivery System-II-(SP)-Dr.S.Pavani, P'Equip:Pharmaceutical Equipment-(RLK)-Dr.R.L.Kalyani, RA: Regulatory Affairs- (SS)-Dr.S.Sireesha

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VAAGDEVI COLLEGE OF PHARMACY

PHARM.D VI YEAR (2023-24)

S.No.	NAME	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL
1	P. LAHARIKA	SUR	GM	ORTHO	CARDIO	PED	ONCO	PSY	GM	PED	DER	ORTHO	SUR
2	D. SANGEETHA												
3	V. VANDANA												
4	M. SANDEEPA												
5	G.SUPRIYA												
6	G.LAVANYA												
7	V.PAVANI	PSY	ORTHO	SUR	PED	GM	ONCO	SUR	DER	CARDIO	PED	GM	ORTHO
8	P.AKHIL												
9	V.SHANTHI												
10	K.SHILPA												
11	M.UMA SREE												
12	P. NAVYASRI												
13	K.DEVIKA	CARDIO	PED	SUR	GM	PSY	ORTHO	GM	PED	SUR	ORTHO	ONCO	DER
14	MUSKAN												
15	R.KEERTHANA												
16	K.KANISHKA												
17	AYESHA												
18	MAIMANATH												
19	K. SAI VAMSHI	DER	ONCO	ORTHO	SUR	PED	GM	ORTHO	PSY	GM	SUR	PED	CARDIO
20	S.RACHANA												
21	ALIYA												
22	T.SRI VARSHA												
23	B. SAI PRIYA												
24	M. SUPRIYA												
25	G. SANDHYA	PED	SUR	GM	CARDIO	ORTHO	GM	PED	SUR	ORTHO	ONCO	DER	PSY
26	UZMA NAZREEN												
27	J. PRANEETHA												
28	NOWRIN												
29	S. RASHMI												

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PHARM.D V YEAR (CLERKSHIP) 2023-24

NAME	SEP	OCT	NOV	DEC	JAN	FEB
M.SHREYA G.ARCHANA L. PRASANNA LAXMI M.JYOTHI RATNA P.SWESHIKHA IQBAL HUSSAIN	GM	ONCO/ ORTHO	PED	PSY/DER	CARD	SUR
V.SREEDHANA RUHI FATIMA SUMAYYA FATHIMA A.KEERTHANA T.SREEJA	ONCO/ ORTHO	PED	PSY/DER	CARD	SUR	GM
R.SRAVANI T.POOJITHA P.PREETHI S.VISHWANATH ASIYA ISRA YASMEEN	PED	PSY/DER	CARD	SUR	GM	ONCO/ ORTHO
K. DEVISHWARI M.GEETHA A.ASHISH SANA SULTANA S.PRATHIBHA	PSY/DER	CARD	SUR	GM	ONCO/ ORTHO	PED
G. KEERTHANA M.HEMA P.REENA B.ALEKYA SAMIM FIRDUSY	CARD	SUR	GM	ONCO/ ORTHO	PED	PSY/DER
L.ROHITH ELIJAH DENNIS M.SATISH G.SONI CH.GAYATRI	SUR	GM	ONCO/ ORTHO	PED	PSY/DER	CARD

GM=GENERAL MEDICINE; PED=PEDIATRICS, ORTHO=ORTHOPEDICS; ONC=ONCOLOGY; SUR=SURGERY; CARD=CARDIOLOGY,PSY=PSYCHIATRY
DER=DERMATOLOGY

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VAAGDEVI COLLEGE OF PHARMACY

PHARM.D IV YEAR PHARMACOTHERAPEUTICS-III PRACTICAL TIME TABLE (2023-24)

NAME	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG
Ch.Tejasri S.Sheranya M.Siri L.Swapna Azizur Rahman Ankit Pramanik B.Sruthi	PED	GM	PSY	AMC	PED	GM	PSY	AMC	PED	GM	PSY	AMC
A.Sandhya Anjum Mahek T.Sravanthi V.Kalyani Abdul Alim Mallick P.Naveen M.Bhavatharani	GM	PSY	AMC	PED	GM	PSY	AMC	PED	GM	PSY	AMC	PED
A.Bhagya Sri K.Havillah Grace G.Likitha Chrysolite Mirajul Islam S.Srinivas D.Shriya Rizwana Taskeen	PSY	AMC	PED	GM	PSY	AMC	PED	GM	PSY	AMC	PED	GM
A.Sravani G.Akshay B.Sahana K.Hari Chandra Prasad Juveriya Fathima B.Nagamani S.Sruthi	AMC	PED	GM	PSY	AMC	PED	GM	PSY	AMC	PED	GM	PSY

PSY=PSYCHIATRY, GM=GENERAL MEDICINE, PED=PEDIATRICS

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PHARMACOTHERAPEUTICS-II (PHARM.D-III YEAR) PRACTICAL TIME TABLE (2023-24)

NAME	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP
Cherukupally Shreya Arella Avanthi Sania Muskaan Gande Shivani Abdul Asif Amaan Gurram Vani	GM/D	PED	DIA	ORTHO	ONC	GM/D	PED	DIA	ORTHO	ONC	GM/D	PED
Gogulakonda Ravalika Erroju Snigdha Varanganti Sindhuja Pocnem Chandrahasini Pamu Venkataramaiah Rajaboina Sindhu	PED	DIA	ORTHO	ONC	GM/D	PED	DIA	ORTHO	ONC	GM/D	PED	DIA
Madhava Rajahamsa Mandala Neha Mandala Nisha Sara Sameen Sidra Nausheen Lyaga Shivani	DIA	ORTHO	ONC	GM/D	PED	DIA	ORTHO	ONC	GM/D	PED	DIA	ORTHO
Muppidoju Susmitha P. Sai Nithin Goud Gudepu Abhigna Najmul Hoque Gurnule Ganesh Abul Kalam Azad	ORTHO	ONC	GM/D	PED	DIA	ORTHO	ONC	GM/D	PED	DIA	ORTHO	ONC
Selim Ahmed Hadi Alom Afridi Alom Kondra Neha Vasam Lahari Mohammed Sohail Mehtaab Bouth Anurag	ONC	GM/D	PED	DIA	ORTHO	ONC	GM/D	PED	DIA	ORTHO	ONC	GM/D

GM/D=GENERAL MEDICINE/DERMATOLOGY; PED=PEDIATRICS, DIA=DIALYSIS, ORTHO=ORTHOPEDICS; ONC=ONCOLOGY

Dr. K.S. SHARVANA BHAVA M.Pharm
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HEAD OF THE DEPARTMENT

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VAAGDEVI COLLEGE OF PHARMACY

PHARM.D II YEAR PHARMACOTHERAPEUTICS-I PRACTICAL TIME TABLE (2023-24)

NAME	OCT	NOV	DEC	JAN	★FEB	MAR★	APR	MAY	JUN	JUL	AUG	SEP
A.Ram Charran Tej	CVS	CVS	PED	PED	GM	GM	CVS	CVS	PED	PED	GM	GM
D. Srinidhi												
S. Nikhitha												
N. Manideepsai												
Arfa Samreen												
D. Harika	PED	PED	GM	GM	CVS	CVS	PED	PED	GM	GM	CVS	CVS
G. Akhila												
G. Navyasri												
R.Mounika												
E. Swetha												
S. Vishnu Priya	GM	GM	CVS	CVS	PED	PED	GM	GM	CVS	CVS	PED	PED
Rida fathima												
B. Sreeja												
N. Manoj												
T. Sudeepthi												
Syeda Atufa Banu												
V. Eekshitha	PED	PED	GM	GM	CVS	CVS	PED	PED	GM	GM	CVS	CVS
K. Saivardhan												
H. Sakshitha												
K. SouryaTeja												
I.Shiva Varma												
P. Vasavi												
Sama Parbin	GM	GM	CVS	CVS	PED	PED	GM	GM	CVS	CVS	PED	PED
Mehabubul Hasan												
Arshiya Tarannum												
Gulzar Hussain												
Sameera Harmain												
T. Sravanthi												
Hashiful Islam												
P. Akhila												

CVS=CARDIOLOGY, GM=GENERAL MEDICINE, PED=PEDIATRIC

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