M. PHARM REVISED SYLLABUS
(2008-2009)

EFFECTIVE FROM 2008-2009
ACADEMIC YEAR ONWARDS

UNIVERSITY COLLEGE OF PHARMACEUTICAL SCIENCES
KAKATIYA UNIVERSITY, WARANGAL-506 009.
KAKATIYA UNIVERSITY
WARANGAL

RULES AND REGULATIONS TO M.PHARM. COURSES OFFERED UNDER SEMESTER SYSTEM

General Schedule

There shall be 16 weeks for each semester and it takes two years to complete the course. III and IV semester contains the project work

Academic Schedule

Each semester will have **4 theory and two practical papers** with **six periods** per week. There also seminars and assignments in I and II semester and comprehensive viva in third semester

Question Paper Pattern

There will be **four questions** in each paper. Each question will have 3 bits

Distribution of marks:
I and II semester (4 theory and 2 practical and seminar and assignment)
Theory

Four question	4x25=100 marks

Practicals:

	100 marks
Seminar	50 marks
Assignments	50 marks
III semester seminar	50 marks

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Comprehensive viva voice		50 marks
IV semester	seminar	50marks
	Disseratation evaluation	200 marks
Disseration viva voice		50 marks

Promotion:

A student has to not only put in 75% of attendance and register for examination for each semester but also appear all paper in each semester for promotion to next semester. A students with 4 papers has block lag can be promoted to M.Pharm second year. There shall be no supplementary examinations.

The minimum pass marks shall be 50% in each paper (Theory & Practicals) separately.

Award of division

Aggregate marks of all the semesters:

I Division with Distinction	-----	75% and above
I Division	.....	60% and above and below 70%
II Division	.....	55% and above and below 60%
III Division (PASS)	.....	50%

A candidate in order to become eligible for I/II division shall be required to pass all the papers of final semester in one attempt, besides passing I/II/III semester papers, either earlier to or along with the final semester.

Whenever the syllabi and scheme of examination are changed, in such cases two examinations will be conducted as per old syllabus and scheme. Thereafter, the candidates who have availed/ not availed and not qualified shall have to take the backlog papers as per the changed syllabi and scheme of examination.

The candidates who could not put up required percentage of attendance and detained, however be eligible to seek readmission in the same semester (with at least 40% of attendance in aggregate). Such students have to pay 50% of the tuition fee prescribed.

Distributions of papers:

I semester	.....	All papers compulsory
II semester	.....	All papers compulsory
III semester (Seminar Comprehensive viva voice)		
IV Semester		project work

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Improvement:

a) Improvement during the course of study

"A candidate who has passed in the papers of I/II/ semesters completely can improve his /her performances in one or more papers of I/II/ semesters in the immediately following examination with the provision to retain the better of the two".

Important Guidelines:

1. There shall be four major subjects and two practical during the first two semesters.

2. One seminar and one assignment will be conducted during each semester (I&II). Each will be evaluated for 50 marks by three average of it is taken for awarding marks.

3. One seminar pertaining to the topic of dissertation including concept, literature plan of work will be conducted at the end of IIIrd semester and will be evaluated by minimum of three PG teachers which would include the concerned supervisor. The average marks will be taken into account.

4. Thesis marks will be awarded only by the external examiners.

5. The viva-voce marks are to be awarded by the supervisor and external examiner jointly.

6. Comprehensive viva shall be conducted at the end of third semester and evaluated by the external examiner and all faculty members within each specialization.

7. One assignment related to specialization (related to specific topics and supported by original articles) is given in each of I & II semesters, which shall be evaluated by two examiners. Average marks is taken into account.

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8. One seminars each semester during I & II shall be conducted before all the faculty and PG students and will be evaluated by minimum of three PG teachers. Average marks are taken into account.

9. There shall be two practical examinations each of six hours duration on two consecutive days at the end of first and second semesters. There shall be one internal examiner for each practical examination. However, the external examiner shall be common for both the practical examinations.

SPECIALIZATIONS:

1. Pharmaceutics
2. Pharmaceutical Chemistry
3. Pharmacognosy
4. Pharmacology
5. Industrial Pharmacy
6. Pharmacy Practice
7. Pharmaceutical analysis

M.Pharm. I Semester

Theory	Marks	Lectures	Tutorials	Practicals
Paper – I	100	3	2	-
Paper – II	100	3	2	-
Paper – III	100	3	2	-
Paper – IV	100	3	2	-
Practicals				
Paper – I	100	-	-	9
Paper – II	100	-	-	9
Seminar	50			
Assignment	50			
Total	**700**	**12**	**8**	**18**

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M.PHARM. (PHARMACEUTICAL ANALYSIS)

I SEMESTER

Theory		hours/week
1.1.T	Advanced Pharmaceutical analytical techniques	3
1.2.T	Pharmaceutical Analysis-I	3
1.3.T	Quality control of Pharmaceutical dosage forms	3
1.4.T	Biological standardization	3

Practicals

1.1.P	Advanced Pharmaceutical analytical techniques	9
1.2.P	Pharmaceutical Analysis-I	9

II SEMESTER

Theory

2.1.T	Quality assurance	3
2.2.T	Pharmaceutical Analysis-II	3
2.3.T	Analytical method development and validation	3
2.4.T	Regulatory Affairs	3

Practicals

2.1. P	Analytical method development and validation	9
2.2.P.	Pharmaceutical Analysis-II	9

III SEMESTER

Comprehensive Viva-voce
Seminar on Dissertation Topic (Project Work) (Introductory)

IV SEMESTER

Final Seminar of Dissertation (Results)
Dissertation

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M.Pharm. II Semester

Theory	Marks	Lectures	Tutorials	Practicals
Paper – I	100	3	2	-
Paper – II	100	3	2	-
Paper – III	100	3	2	-
Paper – IV	100	3	2	-
Practicals				
Paper – I	100	-	-	9
Paper – II	100	-	-	9
Seminar	50			
Assignment	50			
Total	**700**	**12**	**8**	**18**

M.Pharm. III Semester

	Marks
Seminar (Pertaining to the topic of research and work plan)	50
Comprehensive viva-voce	50
Total	**100**

M.Pharm. IV Semester

	Marks
Seminar (Experimental Work, Results, Discussion and Conclusion)	50
Dissertation evaluation	200
Dissertation Viva-Voce	50
Total	**300**

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1.1. T. ADVANCED PHARMACEUTICAL ANALYTICAL TECHNIQUES

Unit I

a. Thin Layer Chromatography: Theory, preparation, procedures, detection of compounds and applications for pharmaceutical analysis
b. HPTLC: Theory, instrumentation and various applications for pharmaceutical and herbal products.
c. Paper Chromatography: Theory, different techniques employed, filter papers used, qualitative and quantitative analysis
d. Electrophoresis: Theory, instrumentation and various techniques (e.g. paper, capillary electrophoresis etc.) applications for analysis pharmaceuticals.

Unit II

a. Gas Chromatography: Introduction, fundamentals, instrumentation, columns: Preparation and operation, detectors, derivitazation and pharmaceutical applications: GC-MS and application mentioned for the substances in IP.
b. HPLC: Principles and instrumentation, columns and detectors used, pharmaceutical applications.
c. LC-MS, MS-MS and its applications for analysis or drug substances as mentioned in IP, BP and USP.

Unit III

a. UV-Visible spectroscopy : Introduction, electromagnetic spectrum, absorbance laws and limitations, instrumentation-design and working principle, chromophore concept, auxochromes, Wood-Fisher rules for calculating absorption maximum, applications of UV-Visible spectroscopy.
b. IR spectroscopy: Basic principles-Molecular vibrations, vibrational frequency, factors influencing vibrational frequencies, sampling techniques, instrumentation, interpretation of spectra, FT-IR, theory and applications.

Unit IV

Mass spectroscopy: Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution, interpretation of spectra and applications for identification and structure determination.

Unit V

NMR: Theory, instrumentation, and it applications in analysis of pharmaceuticals

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REFERENCES:

1) Instrumental Methods of Chemical Analysis - B.K Sharma
2) Organic spectroscopy - Y.R Sharma
3) A Text book of Pharmaceutical Analysis - Kerrenth A. Connors
4) Vogel's Textbook of Qualitative Chemical Analysis - A.I. Vogel
5) Practical Pharmaceutical Chemistry - A.H. Beckett and J.B. Stenlake
6) Organic Chemistry - I. L. Finar
7) Organic spectroscopy - William Kemp
8) Quantitative Analysis of Drugs - D.C. Garrett
9) Quantitative Analysis of Drugs in Pharmaceutical Formulations - P. D. Sethi
10) Spectrophotometric identification of Organic Compounds - Silverstein
11) HPTLC - P.D. Seth
12) Indian Pharmacopoeia - 2007

Practicals

1.1 P Advanced Pharmaceutical analytical techniques: The experiments should be conducted based on theory

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1.2.T. PHARMACEUTICAL ANALYSIS – I

Unit I

An advanced study of the principles and procedures involved in Non – aqueous, Complexometric, Oxidation – reduction and Diazotization methods

Unit II

An advanced study of the principles and procedures involved in the electrometric methods: Conductometry, Potentiometry, Polarography and Amperometry

Unit III

Detailed study of the principles and procedures involved in the quantitative determination of the organic functional groups: Amines, Aldehydes, Ketones, Ester and Hydroxy

Unit IV

Principles and procedures involved in using the following reagents in pharmaceutical analysis with suitable examples

i. MBTH(3-methyl – 2- benzothiazolone hydrazone)
ii. F.C. Reagent (Folin – Ciocalteau)
iii. PDAB (Para Dimethyl Amnio Benzaldehyde)
iv. 2,6 – Dichloroquinone Chlorimide
v. 2,3,5 triphenyl tetrazolium salt
vi. 1,2 napthoquinone-4-sulfonate reagent

Unit V

Principles and Procedures involved in quantitative determination of various pharmaceutical preparations and dosage forms of the Alkaloids (Pilocarpine and quinine sulphate) Antibiotics (Cephalosporins, Griseofulvin), Vitamins (Vitamin A and Vitamin E), Glycosides (Sennoside and Diosgenin), Steroids (dexamethasone and estrogens) and Diuretics (Spiranolactone, Frusemide).

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. Conners
9) Journals (Indian Drugs, IJPS etc.)

Practicals

1.2 P Pharmaceutical analysis-I: The experiments should be conducted based on theory

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1.3.T. QUALITY CONTROL OF PHARMACEUTICAL DOSAGE FORMS

Analysis of Pharmaceutical Dosage form monographs as mentioned in various Pharmacopoeias (I.P., B.P., E.P and U.S.P)

Unit I

Solid dosage forms (Tablets, Capsules, Powders), Semisolid dosage forms (Ointments, Creams)

Unit II

Liquid oral preparations,(suspensions, gels, Emulsions, solutions and elixirs) Eye/Ear and Nasal Drops

Unit III

Parenterals (large volume and small volumes), Inhalations (Aerosols, Nebulizers)

Unit IV

Topical preparations, Transdermal drug delivery systems, Sprays, Suppositories, Pessaries, Surgical Dressings, Novel Drug Delivery Systems

Unit V

Various in process quality control tests carried on the following dosage forms
Tablets, capsules, parentrals, Liquid orals and other dosage forms

RECOMMENDED BOOKS:

1) Remington's Pharmaceutical Sciences – Alfonso and Gennaro
2) Microbiological Assays – Barton J. Wright
3) Pharmaceutical Chemistry – Becket and Stanlake
4) Quantitative Analysis of Drugs in Pharmaceutical Formulations – P.D. Sethi
5) Pharmaceutical Analysis – Higuchi, Bechmman and Hassan
6) Theory and Practice of Industrial Pharmacy – Liebermann and Lachmann
7) Indian Pharmacopoeia – 1996

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1.4 T. BIOLOGICAL STANDARDIZATION

Unit-I. Detailed study of principles & procedures involved in bio assay of.

(a) Heparin, Insulin, Posterior Pituitary
(b) Diphtheria, Typhoid0

Unit-II. Principles and Procedures involved in Biological tests of the following.

(a) Living contaminants in vaccines.
(b) Endotoxins
(c) Histamine like substances
(d) Toxic elements

Unit-III Microbiological assay of
(a) Vitamins e.g.cyanocobalamin
(b) Antibiotics such as Neomycin sulphate,
(c) Vaccine e.g. Diptheria

Unit-IV

a) Biological assay evaluation of oxytocin, rabbies vaccine and tetanus antitoxin

b) Radioimmuno assay: General principles, scope of limitations R.I.A of Insulin and digitalis, ELISA (instrumentation, Principle and application for analysis of pharmaceuticals)

C) Radiopharmaceuticals (indium (^{111}In) pentetate injection, strontium (^{89}Sr) chloride injection, Technitium (^{99m}Tc)macrosalib injection

Unit-V

Detailed study of principles & procedures involved in bio assay of estrogens, Hepatitis vaccine, Biological assay of Gas-gangrene antitoxin, Blood and blood related products(Anti-blood grouping scrum, Human albumin, Human plasma protein fraction, Human coagulation factors), Biotechnology products(erythropoietin, Interferons, streptokinase).

Books Material Recommended

1. Indian Pharmacopoeia, 2007 Controller of Publications, Govt. of India, New Delhi.
2. Bochmman & Hassan, Pharmaceutical Analysis, edited by: Higuchi.
3. D C Garrott, Quantitative Analysis of drugs. CBS Publishers, New Delhi.
4. R V Smith, J T Stewart, Textbook of Bio Pharmaceutical Analysis.
5. Pulok K Mukherjee: Quality Control of Herbal Drugs, Business Horizons Pharmaceutical Publishers, New Delhi.
6. British Pharmacopeia, Department of Health U.K.
7. Classification of cosmetic raw materials

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2.1. QUALITY ASSURANCE

Unit I

Concept of quality assurance, total quality management, philosophy of GMP, cGMP and GLP, organization and functioning of accreditation bodies: ISO 9000, ISO 14000, NBL and OSHA 18000

Unit II

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

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

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

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.

TEXT BOOKS:

1. The International Pharmacopoeia Vol 1,2,3,4, 3rd edition: General methods of analysis quality specifications for Pharmaceutical substances, Excipients, dosage forms.

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2.2. PHARMACEUTICAL ANALYSIS - II

Unit I

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

a) Elemental analysis such as determination of sodium, potassium, calcium, phosphorous, sulphur, chlorine, bromine and Iodine,
b) X-ray spectroscopy: x-ray diffraction, principle, instrumentation , method and application for the analysis of pharmaceuticals
C) Optical rotator dispersion technique for the analysis of chiral compounds

Unit III

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

Thermal method of analysis, theory, instrumentation and applications of Thermo gravimetric analysis (TGA), Differential Thermal analysis (DTA) and DSC.

Unit V

Identification and quantitative determination of preservatives, Antioxidants, Colouring materials, Emulsifiers and Stabilizers in Pharmaceutical formulation

Methodology involved

a. Moisture content determination in dosage forms
b. Alcohol determination
c. Essential oil determination
d. 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. Conners

2.2. P. Pharmaceutical Analysis – II. The experiments should be conducted based on theory

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2. Quality Assurance of Pharmaceuticals. A compendium of guidelines and related material Vol.I and Vol.2, WHO (1999)
3. GMP- Mehra
4. Pharmaceutical Process Validation – Berry and Nash

REFERENCE BOOKS:

1. Basic tests for Pharmaceutical substances – WHO (1988)
2. Basic tests for Pharmaceutical substances – WHO (1991)
3. How to practice GMP's – P.P.Sharma
4. The Drugs and Cosmetic Act 1940 – Vijay Malik
5. Q.A. Manual - D.H. Shah
6. SOP Guide lines - D.H. Shah
7. Quality Assurance Guide - OPP

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2. 4 . REGULATORY AFFAIRS

1. New Drug Application: Steps involved in the development of a new drug. Procedure for submission of new drug application (NDA) and abbreviated NDA. Requirements and guidelines on clinical trials for import and manufacture of drug products as per Drugs and Cosmetics act. Clinical trials, study design, documentation and interpretation.

2. Documentation: Importance of documentation, statutory requirement and procedure for documentation, description of documents generated in manufacture of pharmaceutical dosage form.

3. Current good manufacturing practices (CGMP) as per WHO.

4. Good laboratory practices (GLP)

5. ISO 9000 series, GATT, TQM

6. Intellectual property rights and Patent laws in India

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2.3. ANALYTICAL METHOD DEVELOPMENT AND VALIDATION

Unit-I

Analytical method development: Introduction, quantification of calibration of various analytical instruments for drug analysis and maintenance of Instruments

Unit-II

Analytical methods development, optimization and validation using the instruments such as UV/Vis spectrometer, FT-IR spectrometer for pharmaceutical dosage forms, active pharmaceutical ingredients (API) and pharmaceutical aids.

Unit-III

Development of analytical method, optimization and validation using Paper and Thin layer chromatography, HPLC, LC-MS, GLC, GC-MS, HPTLC, Capillary electrophoresis for pharmaceutical dosage forms and bulk drugs.

Unit-IV

Drug analysis from biological samples, extraction using various extraction techniques and Development, optimization and validation of bioanalytical method.

Unit V

Validations

Concept, Type of Validations, Master plan, Protocol for process, cleaning, equipment and facilities including sterile and non-sterile areas, analytical method validations, vendor validation and audit, sample testing and trade analysis.

Prevalidation activities: Protocol preparations, protocol executions, Deviations and Change Controls, Summary and Certification, Revalidations.

Recommended books:

1. Analytical Method Development and Validation, Michael Swartz, Swartz Swartz, Michael Swartz, CRC press.1997
2. Modern HPLC for practicing scientists, Michael W.Dong (google.com)
3. Practical HPLC method development 2nd edition , Llyod R.synder (google.com)
4. Pharmaceutical process validation, NashRA and Watcher AH, CBS publishers and Distributors, Newdelhi
5. Modern Pharmaceutical analysis, Volume1-4, Satish Ahuja, CBS publishers and Distributors, Newdelhi

2.1. P. Analytical method development and validation: The experiments should be conducted based on theory

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M. Pharm (Pharmaceutics)

I SEMESTER	Th. hrs/week	Pr. hrs/week
1. Bio Pharmaceutics & Pharmacokinetics	3	9
2. Pharmaceutical Formulation Technology *	3	9
3. Physical Pharmaceutics *	3	-
4. Quality Assurance (optional)	3	-
5. Seminars/Assignments	3	3

II SEMESTER		
6. Novel Drug Delivery Systems-I	3	9
7. Novel Drug Delivery Systems-II *	3	9
8. Pharmaceutical Equipment *	3	-
9. Cosmetic Technology/ Regulatory affairs (optional)	3	-
10. Seminars/Assignments	3	3

*** Practicals for both papers**

III SEMESTER

Comprehensive Viva-voce
Seminar on Dissertation Topic (Project Work) (Introductory)

IV SEMESTER

Final Seminar on Dissertation (Results)
Dissertation

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I - Bio Pharmaceutics & Pharmacokinetics: 3 hrs/week

1. Bio-availability, Bioequivalence and Therapeutic equivalence: Designing of bioavailability studies and interpretation of results. Tests of significance, Test, ANOVA.

2. Physico-Chemical properties affecting bioavailability, pH-partition theory, dissolution, surface area, adsorption, complexation, polymorphism etc., and techniques of enhancing dissolution rate.

3. Formulation factors affecting bioavailability of drug in dosage forms of tablets, capsules, Parenterals, liquid orals and topical dosage forms.

4. Basic concepts of Pharmacokinetics: Compartmental models: one, two and non compartmental approaches to pharmacokinetics. Recent trends, merits and limitation of these approaches. Application of these models to determine the various pharmacokinetic parameters pertaining to:

   i. Absorption: (wherever applicable) Absorption rate constant. Absorption half life, lag time and extent of absorption, AUC.

   ii. Distribution: Apparent volume of distribution and its determination.

   iii. Metabolism: Metabolic rate constant and its determination.

   iv. Elimination: Over all apparent elimination rate constant and half life.

   Under the following conditions:

   a) Intra venous bolus injection

   b) Intra venous infusion

   c) Single dose oral administration

   d) Multiple dose injections

   e) Multiple dosage oral administration

   v. Non invasive methods of estimating pharmacokinetic parameters with emphasis on salivary and urinary compartments.

   vi. Concept of clearance: Organ clearance, total clearance, hepatic clearance, gut wall clearance, lung clearance and renal clearance.

5. Non-linear Pharmacokinetics: concepts of linear and non linear pharmacokinetics, Michaelis-Menten kinetic characteristics. Basic kinetic parameters, possible causes of non induction, non linear binding, non linearity of pharmacological response.

6. Non compartmental Pharmacokinetics.

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7. Time dependent Pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chrono Pharmacokinetics.

8. Clinical Pharmacokinetics: Altered kinetics in pregnancy, child birth, infants and geriatrics, liver, and renal diseased states.

Practicals: Based on Theory.

II- PHARMACEUTICAL FORMULATION TECHNOLOGY 3hrs/week

1. Performulation studies:

a) Goals of preformulation, preformulation parameters, Methodology, Solid state properties, Solubility and Partition coefficient, Drug excipient compatibility.
b) Excipients used in pharmaceutical dosage forms.
c) Properties and selection criteria for various excipients like surfactant, viscosity promoters, diluents, coating materials, plasticizers, preservatives, flavors and colours.

2. Formulation Development:

a) **Solid dosage forms:**Improved production techniques for tablets: New materials process, equipments improvements, high shear mixers, compression machines, coating machines, coating techniques in tablet technology for product development , physics of tablet compression, computerization for in process quality control of tablets, types of tablets and their manufacture. Formulations, production and evaluation of hard and soft gelatin capsules.

b) **Powder dosage forms:** Formulation development and manufacture of powder dosage form for internal and external use including inhalations dosage forms.

c) **Liquid and Semi-solid dosage forms:** Recent advances in formulation aspects and manufacturing of monophasic dosage forms. Recent advances in formulation aspects and manufacturing of suspensions, dry syrups and semi-solid dosage forms.

d) **Parenteral dosage forms:** Advances in materials and production techniques, filling machines, sterilizers and aseptic processing. Manufacturing of small and large volume parenterals and quality control.

e) **Aerosols:** Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers and formulation aspects in aerosol formulation, Manufacture and quality control.

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f) **Aseptic processing operation:** Introduction, contamination control, microbial environmental monitoring, microbiological testing of water, Microbiological air testing, characterization of aseptic process, media and incubation condition, theoretical evaluation of aseptic operations.

III. Physical Pharmaceutics: 3hrs/week

1. **Theory of Solubilization and Solubilization Techniques:** Solubility and solubilization of non electrolytes, solubilization by the use of surfactants, cosolvents, complexation, drug derivatisation and solid state manipulation.

2. **Theories of Dispersion:** Solid-liquid dispersion: adsorption, wetting, crystal growth mechanisms and prevention of crystal growth.

3. **Emulsion:** Formation and stability of emulsion with special emphasis on electrical theory, HLB theory and dielectric properties. Preparation, evaluation and applications of multiple and microemulsions.

4. **Solid State Properties:** Crystal properties and polymorphism, Techniques for study of Crystal properties, solid state stability, flow properties of powders, segregation and its importance.

5. **Theories of Compaction and Compression:** Compression, consolidation strength of granules, compression and consolidation under high loads, effects of friction, distribution of forces in compaction, force volume relationships, Heckel plots, compaction profiles, energy involved in compaction, strength of tablet, crushing strength, friability, lamination, instrumentation of tablet machines.

6. **Polymer Science:** Polymer structure, classification and Properties of polymers, thermodynamics of polymer solution, phase separation, polymers in solid state. Applications of polymers in pharmaceutical formulations.

7. **Diffusion and Dissolution:** Diffusion, steady state diffusion procedures and apparatus. Diffusion principles in biological systems, Thermodynamics of diffusion. Dissolution: Basic theories of dissolution, models. Sink conditions in dissolution and its importance. In-vitro-in-vivo- correlations. Dissolution testing for Novel drug delivery systems.

8. **Kinetics and Drugs stability:** Stability calculations, rate equation, kinetics of decomposition, strategy of stability testing, methods of stabilization, methods of accelerated stability testing in dosage forms. Freeze-thaw methods, centrifugal methods, temperature and humidity control.

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IV. Quality Assurance: 3hrs/week

1. **Plant Design:** Design of manufacturing facility as per current good manufacturing practices for the bulk production of different pharmaceutical dosage forms.

2. **Equipment Validation:** Installation, validation and maintenance of typical equipment used in bulk manufacture of pharmaceutical dosage forms with reference to GMP requirement.

3. **Process Validation:** Regulatory basis, validation of solid dosage forms, liquid dosage forms, and sterile products, Process validation of raw materials, validation of analytical methods.

4. **Quality Control:** Process controls involved in manufacturing process of pharmaceutical dosage forms, statistical quality control charts and its applications in process control. Testing programme and methods for testing quality of pharmaceutical dosage forms. Adulteration and misbranding.

5. **Stability studies:** ICH guidelines and stability protocols for different pharmaceutical dosage forms.

6. **Industrial Safety:** Industrial hazards due to fire accidents, mechanical and electrical equipment, chemicals and pharmaceuticals. Monitoring and prevention systems.

7. **Applications of optimization techniques:** Optimization parameters, statistical design and techniques in product development and evaluation. Production optimization and its importance.

V – Seminars & Assignments

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II – Semester

IV-Novel Drug Delivery Systems - I

1. **Review of Fundamentals of controlled drug delivery systems:** Fundamentals, rationale of sustained/controlled drug delivery, factors influencing the design and performance of sustained/controlled release products, Pharmacokinetic/ Pharmacodynamic basis of controlled drug delivery. Types and structure of polymers, Use of polymers and biocompatible polymers in controlled release of active agents.

2. **Drug targeting principles and approaches:** Active and passive targeting, Tumor targeting, Bone marrow targeting, cell surface biochemistry and molecular basis of targeting. Tumourbiology-Extra cellular matrix- knowledge of cell adhesion molecules- selectins and fibronectins -lectins for tumour targeting.

   Monoclonal antibodies and engineered antibodies for drug delivery. Antibody-drug conjugates, Limitations of antibody targeting.

   Brain targeting, Blood brain barrier, structure, role in drug transport, targets for targeting.

   Receptor-structure, endocytosis, receptor mediated endocytosis and transcytosis.

   Knowledge of drug targeting through chemical drug delivery approaches to different organs like brain, eye, lung and lever etc. Colon specific systems.

3. Transdermal drug delivery systems, Iontophoresis, Electroporation and Microneedles, Gastro Retentive Drug Delivery System, oro dispersible tablets, Dendrimers.

4. **Design and fabrication of controlled release drug delivery system:** Principle involved and formulation of: Oral dosage forms – Diffusion system, Reservoir devices, Osmotic systems, Systems utilizing dissolution and ion exchange resins, prodrugs, Multiple Emulsions.

5. Parenteral dosage forms, intramuscular injections, implantable therapeutic systems, Transmucosal systems and mucoadhesive systems, Nasal delivery, intravaginal and intrauterine systems, Lung delivery systems. Ocular drug delivery, drug delivery to GIT.

6. **Carrier Based Delivery Systems:** Principle involved and formulation of Micro particulate drug carriers, Liposomes, Niosomes, Microspheres, Magnetic microspheres, Nanoparticles. Resealed erythrocytes.

Practicals: Based on theory

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VII- NOVEL DRUG DELIVERY SYSTEMS - II

3 hrs/week

1. Cell membranes, epithelial barriers of Drug absorption and physiological factors affecting oral bioavailability.

    a. Plasma membrane – Phospholipids bilayer, membrane modulation of fluidity modelsvproteins.
    b. Epithlia – cell junctions – structure and role in drug absorption.
    c. Transport across cell membranes – efflux transporter systems (multi drug resistance).

2.

    a) Inter cellular routes of absorption, persorption.
    b) M cells and peyer's patches in GIT, mucus – structure and composition.
    c) Permeation enhancers – classification and mode of action.
    d. Lymphatic transport of drugs.

3. **Nucleic acid based therapeutic delivery systems:** Gene therapy, introduction, (ex vivo & in-vivo gene therapy) potential target diseases for gene therapy (inherited disorder and cancer), gene expression system (viral & non viral gene transfer), gene delivery systems (liposomal), biodistribution and pharmacokinetics. Clinical applications. Knowledge of therapeutic antisense molecules and aptamers as drugs of future.

4. **Genomics, Proteomics:** Definitions of genomics and proteomics and Bioinformatics. Brief Knowledge of Human genome project –Pharmacogenomics-genetic Polymorphisms influencing drug disposition and effect on drug response.

5. **Delivery of peptides and proteins/Biotechnology based drugs:-**Formulation aspects. Preformulation studies and problems: Protectants, delivery kinetics. Overview of delivery systems, site specific proteins, Stability problems, Evaluation of recombinant proteins. Knowledge of engineered proteins-techniques of getting engineered Proteins by DNA technology. Insulin derivatives like- Lispro, tissue plasminogen activator like reteplase. Antibodies, derivatives of antibodies Myelotarg, Herceptin, and Absciximab (Reopro).

6. **Vaccine Delivery:** Evidence and mechanism of uptake and transport of antigens. Delivery systems used to promote uptake. Absorption enhancers, Lipid carrier systems, oral immunization, peyer's patches, common mucosal immune system, controlled release micro particles for vaccine development, single dose vaccine delivery systems using biodegradable polymers. Knowledge of peptide based and nucleic acid based vaccines. Antigen adjuvants in vaccine formulations.

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VIII. Pharmaceutical Equipment: 3hrs/week

Installation, Validation, Maintenance and working of the following:

1) **Tablet Machines**: Rotary tablet, Multi punch
2) **Coating Equipment**: Pans, fluidized bed
3) **Dryers**: Freeze, spray, fluidized bed and tray dryer
4) **Granulators**: Rapid mixer, extruder-spheronizer
5) **Mixers/Milling**: Planetary, double cone, triple roller mill, colloidal mill
6) **Filters:** Plate and frame press, membrane filters, air filtration system (Laminar flow) and Aseptic Room
7) **Sterilization:** Autoclave
8) **Homogenizers** and High Pressure Homogenizer

IX. COSMETIC TECHNOLOGY/REGULATORY AFFAIRS (Optinal) 3 hrs/week

1. **Preformulations studies:** Preformulation studies and stability testing of Cosmetic products – Shelf–life determination of Cosmetic products, Effects of environmental factors like light, temperatures etc., on product stability.
2. **Raw materials used for Cosmetic preparation:** Detailed knowledge of various raw materials used in cosmetic industry, like surfactants, humectants, perfumes and colours.
3. **Good Manufacturing Practices and Regulatory Requirements:** Knowledge of the Regulatory Standards governing Cosmetic products in India as well as International Markets.
4. **Hair Care Products:** Introduction, Hair structure, Antidandruff shampoos, setting lotion, Hair dyes.
5. **Skin Care Products:** Introduction, anatomy and physiology of skin, formulation of skin cleaners, moisturizers, sunscreen products, anti acne products, anti-ageing creams.

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6. **Colour cosmetics:** Introduction lip sticks, nail polish, face make-up and eye make-up.

7. **Herbal Cosmetics:** Introduction, use of plants and plant materials in formulation of cosmetics with emphasis on dentifrices, skin care products and personal hygiene products.

8. **Personal Hygiene Products:** Shaving creams and after shave products, Antiperspirants and deodorants.

9. **Safety testing of Cosmetic Products:** Microbiology in Cosmetics.

   Knowledge of the various microbial contaminants in cosmetic products.

   Knowledge of various preservative systems for cosmetic products.

   Selection criteria for preservatives.

   Efficacy and safety testing of preservatives in cosmetic products.

10. **Packaging in Cosmetics:**

    Knowledge of various packaging materials used in cosmetic products.

    Knowledge of various machines used for packing of cosmetic products.

    Contemporary trends in cosmetic packaging.

    Compatibility and stability testing of packaging materials in cosmetic products.

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I – Semester

Biopharmaceutics and Pharmacokinetics (Practicals) (9hrs/week)

1) Calculation of Pharmacokinetic Parameters using one compartment open model in blood when given by
   a) I.V. bolus
   b) Oral administration (Method of Residuals)
   c) I.V. infusion

2) Calculation of Pharmacokinetic parameters using one compartment open model by urinary excretion data:
   a) Rate Excretion method
   b) Sigma Minus method.

3) Calculation of absorption rate constant by Wagner-Nelson method.

4) Calculation of Pharmacokinetic parameters using Two-Compartment open model in blood when given by:
   a) Oral route
   b) I.V. route

5) Effect of formulation factors on Bioavailability of the drug from various dosage forms.

6) Comparison of Invitro-dissolution profiles of marketed preparations.

7) Effect of Polymorphism on drug dissolution

8) Determination of a protein binding of a drug.

9) Effect of Complexation on the solubility and dissolution rate of drug from dosage forms.

10) To conduct a bioequivalence study using plasma/urine/saliva samples.

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I - Semester

Pharmaceutical Formulation Technology & Physical Pharmaceutics 9 hrs/week

1) Preparation and evaluation of Oral suspensions.

2) Preparation and evaluation of Effervescent tablets.

3) Preparation and evaluation of Gel based formulations.

4) Design and evaluation of a Aerosol based formulations.

5) Effect of compression force on tablet hardness and disintegration.

6) Effect of pH of dissolution medium on release rate profile of a drug.

7) Effect of various disintegrating agents and superdisintegrants on hardness, disintegration and dissolution of drug from dosage form.

8) Comparison of drug release from tablets prepared by Dry granulation, wet granulation, and slugging.

9) Comparison of Intrinsic dissolution rate with dissolution rate profile of dosage form.

Physical Pharmaceutics

1) Diffusion study of drug through various Polymeric membranes.

2) Determination of shelf life of a drug using Accelerated stability studies. (Temperature, pH and Humidity).

3) Formulation and evaluation of Multiple and Micro emulsions.

4) Enhancement of Solubilization of Non-electrolytes by
a) Surfactants b) Co-solvents c) Complexation d) Solid dispersion

5) Effect of Compression force on tablet strength, Friability and lamination.

6) Effect of various blends of glidants on flow properties of powders, granules.

7) Measurement of rheological properties of some polymers and study the influence of plasticizers.

8) Measurement of surface tension/interfacial tension to determine the CMC of surfactants.

9) Preparation of polymer solutions & studying the rheological behaviour

10) Drug-excipient interaction study using Differential scanning calorimeter.

11) Determination of log P value

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II - Semester

Novel Drug Delivery Systems – I (Practicals) 9 hrs/week

1) Preparation and evaluation of Microcapsules.
2) Preparation and evaluation of Transdermal patches of a drug.
3) Preparation of evaluation of Liposomal drug delivery systems.
4) Preparation and evaluation of Bioadhesive oral dosage form.
5) Preparation and evaluation of Microspheres.
6) Preparation and evaluation of Buccal drug delivery systems.
7) Design of Protein and peptide drug delivery systems.
8) Development of matrix type sustained release drug delivery.
9) Development of controlled release dosage form for oral use.(Elementary osmotic pump).
10) Preparation and Evaluation of ODT.
11) Preparation and Evaluation of GRDDS.
12) Preparation and evaluation of a Drug immunoconjugate
13) Preparation and evaluation of solid lipid nano particles

Novel Drug Delivery Systems – II & Pharmaceutical Equipment 9 hrs/week

1) Studying the drug transport across Porcine buccal mucola/skin (hydrophilic liphilic drugs)
2) Preparation of liposomal gene delivery systems
3) Preparation of vaccine delivery systems
4) Preparation & Evaluation of stability of protein formulation by gel electrophoresis
5) Studying the role of permeation enhancers in drug transport across biological membranes
6) Preparation of a DNA vaccine
7) Validation of
8) Validation of a dryer
9) Validation of a filtration assembly (rembrne filter)
10) Validation of Rotary tablet machine
11) Validation of Aseptic room
12) Validation of a coating pan

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List of Equipment Required for M. Pharm. Pharmaceutics

1) Digital Disintegration Time apparatus	1.No
2) Dissolution apparatus (U.S.P.) with 8 flasks with paddles and baskets	1.No
3) Mini Rotary Tablet Machine 6/8 station	1.No
4) Hardness Testers Pfizer, Monsanto, advanced digital	1 each
5) Advanced screw guage digital	1.No
6) Top loading Electronic balance 0.1mg sensitivity	1.No
7) U.V spectrophotometer	1.No
8) Moisture determination apparatus digital	1.No
9) Stability Chambers	2.Nos
10) Deep freezer	1.No
11) Centrifuge digital with 3000-4000 rpm	1.No
12) Digital Micropipettes variable volume 20-200 µl	1.No
13) Digital Micropipettes variable volume 100-1000 µl	1.No
14) High Performance liquid Chromatograph with UV detector and soft ware	1.No
15) Sonicator water bath	1.No
16) Probe Sonicator	1.No
17) Research Microscope with photographic arrangement	1.No
18) Rheometer with software preferably Brooke field	1.No
19) Oven Thermostatic	1.No
20) Refrigerator	1.No
21) Electronic Top loading balance 1 mg sensitivity	1.No
22) PH meter digital	1.No
23) Vacuum Oven	1.No
24) Freeze dryer	optional
25) Spray dryer	optional
26) I.R Press	optional
27) All glass distilled water still	1.No
28) Tensile strength apparatus	1.No (optional
29) Cooling Centrifuge	optional
30) Rotary flash evaporator Buchi/Hidolf	1.No
31) Homogenizer high pressure	1.No
32) Magnetic stirrer cum hot plate with digital display	3.Nos
33) Vortex mixer	1.No
34) Mixer	1.No
35) Aseptic cabinet	optional 1.No
36) Gel electrophoresis	optional 1.No
37) Gel documentation system	optional 1.No
38) Injection pump	optional 1.No
39) Coating pan with speed regulator, hot & cold air& spraying device	1.No
40) Diffusion Cells (Franz/Chin type)	6.No
41) Peristaltic pump	1.No
42) Zeta sizer if both branches are available	1.No
43) Sieve shaker digital with sel of sieves	1.No
44) Tray dryer	1.No

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M. Pharm. (Pharmacology)

I – SEMESTER

Theory

1. Advanced Pharmacology – I	3 Hours
2. Advanced Pharmacology – II	3 "
3. Advances in Preclinical Evaluation – I	3 "
4. Pharmacokinetics, Pharmacodynamics & Drug Metabolism (PPDM)	3 "

Practicals

1. Advanced Pharmacology	9 Hours
2. Pharmacokinetics, Pharmacodynamics & Drug Metabolism (PPDM)	9 "

II – SEMESTER

Theory

1. Clinical Pharmacology & Toxicology	3 Hours
2. Advances in Preclinical Evaluation – II	3 "
3. Clinical Research	3 "
4. Molecular and Biochemical Pharmacology Basis of Drug Discovery & Development	3 "

Practicals

1. Clinical Pharmacology & Toxicology	9 Hours
2. Advances in Preclinical Evaluation	9 "

III – SEMESTER

Comprehensive Viva-voce
Seminar on Dissertation Topic (Project Work)

IV – SEMESTER

Final Seminar of Dissertation (Results)
Dissertation

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I - SEMESTER

M.PHARM. (PHARMACOLOGY)
M.I.COL.T.1. ADVANCED PHARMACOLOGY – I
(Theory) 3 Hrs per week

I. Drugs acting at synoptic and neuro effecto junctional sites.
- A. Autonomic & somatic nervous systems.
- B. Muscarinic receptor agonists & antagonists.
- C. Anticholinesterases
- D .Agents acting at NMJ and autonomic ganglia
- E. Sympathomimetic drugs. Catecholamine and adrenergic antagonists.

II. Drugs acting on the Central Nervours System.
- A. Neurotransmission and CNS.
- B.Drugs used in the treatment of
  1. Anxiety & Psychosis
  2. Depression & Mania
  3. Epilepsy
  4. Migraine
  5. CNS degenerative disorders
  6. Parkinson's Disease
  7. Pain

III. Drugs affecting renal and cardiovascular function
- A.Diuretics
- B.Renin & Angiotensin
- C.Drugs used in the treatment of
  1. Myocardial Ischemia
  2. Hypertension
  3. CHF
  4. Hyperlipidemia

IV .Drugs acting on the blood & blood forming organs
- A. Growth factors
- B. Anticoagulants, thrombolytics & antiplatelet drugs.

M.I.COL.T.2. ADVANCED PHARMACOLOGY – II
(Theory) 3 Hrs per week

I Autacoids; Drug therapy of Inflammation
- A. Histamine, Bradykinin & their antagonists
- B .Eicasonoids & PAF
- C. Anti-inflammatory, analgesic & antipyretic agents

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D. Antiasthmatic agents.

II .Drugs affecting gastro intestinal function.

A. Agents for control of acidity and antiulcer drugs

B. Emetics & anti emetics

III. Chemotherapy of

A. Malaria

B. Microbial infections.

(i) Fluroquinolones

(ii) Cephalosporins and other newer agents

(iii) Antifungal and antiviral drugs including Anti HIV drugs.

C. Neoplastic diseases

IV. Oral hypoglycemic agents , Thyroid and anti-thyroid agents.

V. Estrogens, Progestins and Androgens.

M.I.COL.T.3.Advances in Preclinical Evaluation -I

(Theory) 3 Hrs per week

1. Care, handling and breeding techniques of laboratory animals. Regulations for laboratory animal care and ethical requirement. Knowledge of the CPCSEA proforma for performing experiments on animals.

2. Organization of preclinical screening programme (Blind screening)

3. Drug discovery process: Principles, techniques and strategies used in drug discovery .High throughput screening, human genomics.

4. Preclinical and clinical models employed in the screening of new drugs belonging to following categories.

I. Drugs acting on Autonomic nervous system: Sympathomimetics, Parasympathomimetics, Anticholinesterages, anticholinergics, adrenolytics. Muscle relaxants (peripheral)

II. Cardiovascular Pharmacology: Cardiac glycosides, antiarrhythmics, antihypertensives,antiatherosclerotics .

iii. Screening of free radical scavenging activity

IV .Immunopharmacology: Specific (Cell and humoral mediated) and non-specific methods.

v. Drugs for metabolic disorders: Anti-diabetic agents, Hepatoprotective agents, Anti-hyperlipidemic agents

5. Principles of Toxicological evaluations, ED 50, LD50 and TD values,acute,sub-acute and chronic toxicity studies.

6. Introduction to biostatistics, parametric and non parametric tests.

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M.I.COL.T.4. (Theory) –Pharmacokinetics, Pharmacodynamics & Drug Metabolism (PPDM)

(Theory) 3 Hrs per week

1. DRUG ABSORPTION

Factors affecting drug absorption.
Gastro intestinal, percutaneous and rectal absorpton
Absorption kinetics, Wagner Nelson & Loo Riegelman methods
BCS classification – significance

2. DRUG DISTRIBUTION

a. Plasma Protein binding – factors affecting plasma protein binding.
b. Kinetics of protein binding, use of different plots (Scatchard plots etc.,) in characterizing binding kinetics
c. Tissue binding.
d. Transfer of drugs through biological barriers, their therapeutic implication in drug action with emphasis on drug transporters.

3. EXECRETION OF DRUGS

a. Routes of excretion of drugs. Extensive study of contribution of each route with specific examples
b. The role of kidney and factors influencing excretion

4. BIOAVAILABILITY AND BIOEQUIVALENCE OF DRUG PRODUCTS

Factors affecting bioavailability & importance of bioequivalence studies.
Conduct of BE studies – Different approaches
US FDA, EMEA & DCGI guidance on BE studies in fasted, fed conditions
BE study waivers

5. METABOLISM OF DRUGS

a. Phase-I and Phase-II metabolic reactions, microsomal and non-microsomal biotransformation reactions.
b. Drug metabolism in liver, kidney, intestine and other extra-hepatic sites.
c. Drug metabolism in placenta, fetus, new born and aged.

6. FACTORS INFLUENCING DRUG METABOLISM

a. Stereochemical, physicochemical and biological factors.
b. Physiological and environmental factors, species, strain, sex, and age differences.
c. Pathological states.
d. Genetic factors – Introduction to the role of genetics in drug metabolism, Polymorphism in drug oxidation and other metabolic reactions.

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7. CLINICAL PHARMACOKINETICS

i. Revision of basic concepts
ii.Dose – response in man
iii.Influence of renal and hepatic disease on pharmacokinetics
iv.Therapeutic drug monitoring
v.Population pharmacokinetics

8. PHARMACODYNAMICS & PK/PD modeling

a. Drug receptor interaction dynamics – Application of stoichmetry principles
b. Understanding of pharmacokinetics - pharmacodynamic relationships
c. Different pharmacodynamic models: Linear, Emax, Biophase distribution & Indirect response models.

PRACTICALS

M.I.COL.P.1 Advanced Pharmacology Practicals based on M.1.COL.T.1 & T.2

M.I.COL.P.2 Pharmacokinetics, Pharmacodynamics & Drug Metabolism practicals based on (PPDM) theory M.I.COL.T.4

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II - SEMISTER

Paper –1: Clinical Pharmacology & Toxicology

(Theory) 3 Hrs per week

PART 1. Clinical Pharmacology (70% weightage)

1. Adverse Drug Reactions, Drug Interactions and ADR monitoring. Mechanisms of ADR.

2. Pathophysiology and drug therapy of the following disorders.

Schizophrenia, anxiety, depression, epilepsy, Parkinson's, Alzheimer's diseases, migraine hypertension,
angina pectoris, arrhythmias, atherosclerosis, myocardial infaraction, TB, leprosy, leukemia, solid tumors,
lymphomas, psoriasis, respiratory, urinary, g.i. tract infections, endocarditis, fungal and HIV infection,
rheumatoid arthritis, glaucoma, menstrual disorders, menopause.

3. Drug therapy in special populations
   A. Geriatrics
   B. Pediatrics - neonate, infants & adolescents
   C. Pregnancy & Lactation

V. Pharmacogenomics: Interracial and individual variability in drug metabolism and drug action.

PART 2. Principles of Toxicology (30% weightage)

a. Physicochemical, Biochemical and genetic basis of toxicity, principles of toxicokinectics, mutagenesis and carcinogenesis.
b. Guidelines and regulatory agencies – CPCSEA, OECD, FDA, ICH, FHSA, EPA, EEC , WHO etc.,
c. Behavioural, Inhalation, cellular and sub-cellular toxicity hypersensitivity and immune response, range finding tests.
d. Acute, sub-acute and chronic toxicity studies according to guidelines.
e. Application of toxicology in clinical medicine.

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Paper –2: Advances in Preclinical Evaluation - II

(Theory) 3 Hrs per week

1. Bioassays: Basic principles of bioassays,official bioassays,experimental models and statistical designs employed in biological standardization : Acetylcholine, Adrenaline, Digitalis, Heparin, Insulin, d-tubocurarine, Histamine,HCG, Corticotrophine, Vasopressin, oxytocin Biological standardization of vaccines and sera: Pertussis vaccine ,rabies vaccine and Plague vaccine

2. Preclinical evaluation of following categories of drugs.
   i.CNS Pharmacology: Sedatives, hypnotics, anxiolytics, antidepressants, Muscle relaxants (Central). CNS stimulations anticonvulsants, antipsychotics, Noortropics, antiparkinsonian agents,
   ii.Analgesics, antipyretics, anti-inflammatory agents and local anesthetics.
   ii. Gastrointestinal drugs: Antiulcer agents, laxatives
   iii.Respiratory pharmacology: bronchodilators, antitussives,
   iv. Diuretics.
   v. Histamine antagonists
   vi.Reproductive pharmacology: antifertility agents
   vii.Anticancer agents

3. Cell culture technology :
   Animal cell culture – General requirements for establishing the animal cell culture, media, conditions and methods for cell cultures. Applications in Pharmacy.

4. Alternatives to animal screening procedures , Cell-line, patch clamp technique, In-vitro models, molecular biology techniques.

5. Concept of transgenic animals, knockout animals, nude animals, receptor binding assays, principles of immunoassay, patch clamp techniques.

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Paper – 3 : Clinical Research
M.Pharm (Pharmacology / Pharmacy Practice)
(Theory) 3 Hrs per week

1. Introduction to Clinical Research

Definitions and terminology used in clinical trials

- Historical development in clinical research practice
- Drug development process

2. Research Design Methods

Planning and execution of clinical trials, Various Phases of clinical trials

Randomization techniques (Simple randomization, restricted randomization, blocking method 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 study and cross sectional study)

Health outcome measures (Clinical& Physiological, Humanistic and Economic)

2. Bioavailability and Bioequivalence studies

4. Ethics and Guidelines in Biomedical Research

- Ethical Issues in Biomedical Research – Principles of ethics in biomedical research,
- Ethical committee [institutional review board], its constitution and functions,
- Good clinical practice [ICH GCP guidelines, CDSCO regulations, MPA, European, Japan, Health Canada and MHRA guidelines, schedule Y and USFDA in the conduct of clinical trials]

5 Clinical research

- Establishing and functioning of Contract Research Organisation (CRO)
- Roles and responsibilities of clinical trial personnel
- Trial initiation, volunteer recruitment, trial supplies and site management,
- Designing of clinical trial documents
- Monitoring and auditing of clinical trials
- Trial report generation
- Site closure

6. Data Management

Medical Writing and Ethics of publication

Clinical data management (Data entry, data interpretation, data monitoring and auditing)

Reference books (Latest editions)

1. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.

2. Designing Clinical Research. Edtd by Stephen B Hulley, Steven R Cummings

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ASSIGNMENTS FOR CLINICAL RESEARCH

1. Design of Protocol for different types of studies
2. Correspondence procedures for constitution of IRB
3. Designing of informed consent process
4. Designing of CRF
5. Clinical data monitoring

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Paper –4 : Molecular and Biochemical Pharmacology Basis of Drug Discovery & Development

(Theory) 3 Hrs per week

This course primarily focuses on study of the following from molecular and biochemical perspective.
The purpose is to enable the student to understand the trends in modern drug discovery.

General Principles:

1. A general treatment of the approaches to drug design: including the methods of variation, study of the use of biochemical and physiological information involving new drugs.
2. Drug Receptor theory:
   Concept of receptors, theories of drug receptor interaction, forces involved in drug receptor interaction. Receptor polymorphism and dimerization and its importance in drug design.
   A detailed study of Ion channel modulators, Tyrosine kinase and G-Protein coupled receptor, Cyclic neucleotides

Drug Design:

1. Physiochemical properties in relation to biological action and drug design.

   a. Complex of events between drug administration and drug action.
   b. Solubility & partition coefficient.
   c. Rational drug design.
   d. Selected physiochemical properties like isosterism, steric behaviour, ionization, hydrogen bonding, chelation, oxidation- reduction potential, surface actions.

2. Guidelines for drug and analog drug design:

   a. Basic considerations of drug design, de- novo drug design, lead seeking methods, rational drug design.
   b. Structural factors in drug design.
   c. Prodrug concepts.

3. Principles of Computer aided drug design.

4. The quantitative analysis of structure activity relationships
   a. Fundamentals of QSAR- objectives, expressions of biological activity.
   b. QSAR parameters related to chemical structure, correlative methods and analysis of results.

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5. Molecular & Biochemical pharmacology Basis:

a. Application of molecular & biochemical pharmacology to drug design.
b. Introduction to cell structure and function.
c. Cell signaling, organization of signal transduction pathway and biosensors.A detailed study on:
TNF, Apoptosis
Neurosteroids and Cannabinoids
Nitric oxide
ANF, Anti oxidants : Melatonin
Neuropeptide, Substance P
Angiotensin II modulators
Novel peptide based drugs
d. Protein structure prediction and molecular modeling.

PRACTICALS

M.II.COL.P.1 Clinical Pharmacology & Toxicology Practicals based on theory M.1I.COL.T.1.

M.II.COL.P.2 Advances in Preclinical Evaluation Practicals based on theory M.I.COL.T.3.& M.II.COL.T.2.

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REFERENCES

ADVANCED PHARMACOLOGY – I & II

1. Goodman & Gilman's The Pharmcological basis of Therapeutics Ed. J.G. Hardman, L.E. Limbird, P.B. Molinoff and R. W. Ruddon. International Edition. McGraw Hill.
2. Katzung BG, Basic and Clinical Pharmacology, Lange Medical Publication,California
3. H.P.Rang , M.M. Dale, J.M Ritter, P K Moore, Pharmacology, Churchill Livingstone, New York.
4. Roger Walker, Clive Edward, Clinical pharmacy & therapeutics, Churchill Livingstone, New York.
5. Richard D Howlard, Mary J. Mycek, Lippincott Williams & wilkins, Lippincott's illustrated reviewed, Pharmacology. New York
6. Herfindal & Gourtey,Text book of therapeutics-drug,disease and management,Williums and Wilkins publications.
7. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
8. Review articles from published journals.

Advances in Preclinical Evaluation – I & II

1. Vogel HG, Drug Discovery and Evaluation, Springer, Germany
2. Turner RA, Screening Methods in Pharmacology, Academic Press, London
3. Lawrence DR and Bacharach AL, Evaluation of Drug Activities:Pharmacometrics, Academy Press, London.
4. N S Parmar and Shiv Prakash,Screening methods in Pharmacology,Narosa publishing house,New Delhi.
5. S K Gupta, Drug Screening Methods,Jaypee brothers,New Delhi.
6. J H Burn, D.J.Finney and I G Goodwin, Biological Standardisation,Blackwell Scientific Publications, Oxford.
7. Ghosh M N, Fundamentals of experimental Pharmacology,Hilton & Company,Kolkata.
8. M.C.Prabhakar, Experimental Pharmacology, Orient Longman, Chennai
9. SK Kulkarni, Handbook of Experimental Pharmacology, Vallabh Prakashan,New Delhi.
10. R.K.Goel, Practicals in Pharmacology, B.S.Shah Prakashan, Ahmedabad
11. Shayne Cox Gad and Christopher p ,Animal models in toxicology .
12. Hayes, Principles and methods of toxicology.
13. Indian Pharmacopoeia and other pharmacopoeias
14. The UFAW handbook on the care and management of laboratory animals by UFAW.
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16. Review articles from published journals.

Pharmacokinetics, Pharmacodynamics & Drug Metabolism (PPDM)

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
2. Applied Biopharmaceutics & Pharmacokinetics, Eds Leon Shargel et al, Prentice Hall International.
3. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.
4. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
5. Hand Book of Basic Pharmacokinetics. Wolfgang A. Ritschel, Gregory T.. Kearns.Fifth Edition
6. Biopharmaceutics and Pharmacokinetics -A treatise. DM Brahmankar, Sunil B. Jaiswal: Vallabh Prakashan Pitampura, Delhi
7. Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
8. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
9. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
10. Biopharmaceutics and Clinical Pharmacokinetics-An introduction ,by Rebort F
11. Notari Marcel Dekker Inn, New York and Basel.
12. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C.
13. Roylan, Marcel Dekker Inc, New York 1996.
14. Review articles from published journals

Clinical Pharmacology & Toxicology

1. Roger Walker, Clive Edward, Clinical pharmacy & therapeutics, Churchill Livingstone, New York.
2. Textbook of therapeutics, Drug and disease management: Eric T Herfindal, 7th Edn. Williams & Wilkins Publications, 2000
3. Richard D Howlard, Mary J. Mycek, **Lippincott** Williams & wilkins, Lippincott's illustrated reviewed, Pharmacology. New York
4. Goodman & Gilman's The Pharmcological basis of Therapeutics Ed. J.G. Hardman, L.E. Limbird, P.B. Molinoff and R. W. Ruddon. International Edition. McGraw Hill.
5. G Katzung, Basic and Clinical Pharmacology. Bertram, 9th edn Lange Publications, 2004
6. 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.
7. Derelanko and Holinger , CRC Hand book of toxicology
8. Principles of drug action the basis of Pharmacology by Goldstein A, Arrow L. and Kalman ,S.M. 2nd edition. John Wiley & Sons. Incl. New York. 1974 Edition. McGraw Hill.

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10. Niesink R. J. M. de Vries J and Hollingers M.A. toxicology, Principles and applications, CRC Press 1996
11. Matthew J Ellenhorn. Ellenhorns Medical Toxicology –Diagnosis And Treatment of Poisoning. Second edition. Williams and Willkins publication, London
12. V V Pillay. Handbook of Forensic Medicine and Toxicology. Thirteenth edition 2003 Publication, Hyderabad
13. Ellenhorn's "Text book of Toxicology", Eds; Mathew J Ellenhorn et al, 2nd edition, Williams and Wilkins Publications, 1997.
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Molecular and Biochemical Pharmacology Basis of Drug Discovery & Development

1. A guide to chemical basis of drug design by Alfred Rurger (John Willey &Sons)
2. Introduction to the principles of drug design by John Smith and Hawel Williams (Wright PSG).
3. Burgers Medicinal Chemistry – The basis of Medicinal Chemistry by Manfred E.Wolff-1 (John Willey & Sons).
4. Computer assisted drug design by Edward O Olson (American Chemical Society-ACS symposium series 112).
5. Wilson & Giswold's text book of Organic, Medicinal &Pharmaceutical Chemistry.
6. Goodman & Gilman's The Pharmcological basis of Therapeutics Ed. J.G. Hardman, L.E. Limbird, P.B. Molinoff and R. W. Ruddon. International Edition. McGraw Hill.
7. Medicinal chemistry- The role of organic Chemistry in drug research by S.M.Roberts & B.J.Price.
8 .Principles of Medicinal Chemistry by Willium Foye.
9. Current protocols in Molecular biology by Frederick m Ausubel.
10. Human molecular genetics by tomstracham & Andrew P Read.
11. Bioinformatics:Genes ,Proteins & Computers by Cristine Orengo.
12. The Cell – A molecular approach by Geoffrey M Cooper.
13. Genotherapy,Therapeutic mechanism and strategies by Nanoysmith,Tampleton Danilo D Lassic.
14. Fundamentals of Biochemical Pharmacology by Bacq ZM, Capek.
15. Principles of Drug Action, by Goldstein,Amaow and Kalman (John Wiley and Sons, New York).
16. Review articles from published journals

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CLINICAL RESEARCH

1. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. 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.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
6. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
7. Goodman & Gilman's The Pharmcological basis of Therapeutics Ed. J.G.
8. Hardman, L.E. Limbird, P.B. Molinoff and R. W. Ruddon. International Edition. McGraw Hill.
9. A textbook of clinical pharmacy practice- Essential concepts and skills. G Parthasarathi et al, 1st Edn. Orient longman publications, 2004
10. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
11. Designing Clinical Research. Edtd by Stephen B Hulley, Steven R Cummings
12. Clinical Trials & tribulations by Allen E. Cato.
13. Review articles from published journals

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M. Pharm. Pharmaceutical Chemistry Syllabus

Semester – I

Theory Papers:

1. Advanced Organic Chemistry – 1
2. Advanced Medicinal Chemistry – 1
3. Spectroscopic Identification of Organic Compounds
4. Screening methods in Pharmacology

Practicals:

1. Advanced Organic Chemistry -1 Practicals
2. Advanced medicinal Chemistry -1 Practicals

Semester – II

Theory Papers:

1. Advanced Organic Chemistry – 2
2. Advanced Medicinal Chemistry – 2
3. Chemistry of Natural Products
4. Chromatographic Separation technology

Practicals:

1. Chemistry of Natural Products Practicals
2. Advanced Medicinal Chemistry – 2 Practicals

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Pharmaceutical Chemistry

Semester – I

Paper 1: Advanced Organic Chemistry – 1

1. **Nucleophilic aliphatic substitution:** S_N1 and S_N2 reactions; mechanism and kinetics; structure and reactivity; stereochemistry; S_N1 Vs S_N2; role of solvent; substitution Vs elimination; necleophilic substitution – alkyl halides Vs alcohols; S_N1 and rearrangement; stability of carbocations.

2. **Electrophilic aromatic substitution:** reactions; mechanism; proof for the mechanism; sulfonation – a reversible reaction; theory of reactivity; theory or orientation; orientation and synthesis.

3. **Elimination reactions:** E1 and E2 mechanisms of alkyl halides and alcohols; evidence; E1 Vs E2; elimination Vs substitution; 1,1 and 1,2- elimination; E1CB; Saytzeff's rule; Hofmann rule/elimination; stereochemistry of E2 reactions; elimination from alicyclic compounds.

4. **Heterocylic chemistry:** Structures of heterocylic compounds; aromatic and nonaromatic heterocylces; nomenclature; ring sysnthesis; reaction types most frequently used in heterocylic ring sysnthesis; typical reactant combinations; cylcization reactions; displacement at saturated carbon, intramolecular nucleophilic addition to carbonyl groups, intramolecular addition of nucleophiles to other double bonds, cyclization on to triple bonds, radical cyclization, carbine and nitrene cyclization; electrocylic processes in heterocyclic ring synthesis; cycloaddition reactions; 1,3-dipolar cycloaddition, hetero-Diels-Alder reactions, (2+2) cycloaddition.

5. **Heterocylic chemistry:** reactivity of aromatic heterocycles; electrophilic addition at nitrogen; electrophilic, nucleophilic and radical susbstitution at carbon; deprotonation of N-hydrogen; organometallic derivatives; palladium catalyzed reactions; oxidation and reduction of heterocyclic rings.

6. **Five-membered ring compounds with one heteroatom:**Pyrroles, Furans and Thiophenes; Aromaticity; two synthetic methods for each class; reactions; electrophillic substitution; reactions with acids, carbenes, nitrenes; oxidizing and reducing agents; Diels-Alder reaction; photochemical reactions; alkylation of pyroles; metalation of furans; reactions of thiophenes with nucleophiles.

Books Recommended:

1. Organic chemistry – Morrison and Boyd (with study gudie), 11th edition
2. Reaction Mechanisms – Peter Sykes
3. Heterocyclic Chemistry – Joule, Mills and Smith
4. Heterocyclic Chemistry – Thomas Gilchrist.
5. Heterocyclic Chemistry – Raj K. Bansal
6. Text Book of organic chemistry – Clayton, Greeves, Warren and Wothers.

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Semester – II
Paper 2: Advanced Medicinal Chemistry – 1

1. Genesis of new drugs:
i) A brief review of the following topics: sources of new drugs; leads from natural products; molecular modifications; random screening; high throught put screening; insilico screening; structural features and pharmacological acivity; prodrugs; soft drugs; isosterism.
ii) A brief account of drug discovery by recombinant DNA technology.

2. Drug Design:
i) QSAR in drug design:
a) Phisical propertics related to potency.
b) Calculation, measurements and significance of various parameter used in QSAR – (Lipophilicity, steric, Electronic effects). c) applications of Hansch Analysis
ii) Computers in drug design: Introduction; computer graphics and molecular visualization; computational chemistry overview, force fielf methods; geometry optimization; conformational searching; molecular dynamics simulations; quantum mechanics; structure based drug design and Pharmacophore perception, predictive ADME.

3. A study of:
i) β-adrenergic blockers ii) ACE inhibitors iii) synthesis of propranolol, hydralazine, minoxidil, captopril, lisinopril

4. A Study of
i) H1-antagonists ii) H2-antagonists iii) Gastric-proton pump inhibitors iv) Synthesis of levocitrizine, ranitidine, omeprazole

5. A study of:
i) Analgesics (non-opioid) and antipyretics
ii) Non-steroidal anti-inflammatory agents
iii) sysnthesis of paracetamol, ibuprofen, aceclfenac

6. A study of:
i) Anti-cancer agents ii) anti Viral agents iii) Immunosupressants and immunostimulatns
iv) Synthesis of chlorambucil, methotrexate, stauvudine

NOTE: "A study of" includes an account of their origin and development, classification, structures, mechanism of action, SAR, uses and toxicity.

Books Recommended:

1. Wilson and Gisvold's text book of pharmaceutical organic medicinal chemistry
2. Foye's principles of medicinal chemistry
3. Burger's medicinal chemistry and drug discovery
4. Organic chemistry of synthetic drugs – Lednier

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Paper 3: Spectroscopic identification of organic compounds

A brief account of the basic principles involved & instrumentation, and a detailed study of applications of the following spectroscopic techniques in the determination of structure of the following classes of compounds with the help of simple examples:

i) Alkanes ii) Cycloalkanes iii) Alkenes iv) Aldehydes and ketones v) Alcohols vi) Carboxylic acids vii) Phenols viii) Amines ix) Simple Heterocyclic Compounds

1. UV & IR spectroscopy
2. ^{1}H NMR (proton NMR)
3. ^{13}C NMR
4. Mass spectrometry
5. A brief account of the two dimensional NMR techniques like DEPT, COSY, HMQC, HETCOR, HMBC, TOCSY.
6. Problems and their solution – simple problems dealing with structure determination to be worked out.

Note:

1. The aim of this course is to train the student in the spectroscopic identification of organic compounds. Therefore, the emphasis while teaching the subject should be on the applications of the techniques.
2. The theory behind 2D-NMR techniques shall not be taught
3. The use of 2D-NMR techniques to confirm the structural features/assignments of the compounds alone will be emphasized, preferably by giving simple examples.
4. Unit-6: Problems given in Morrison & Boyd and Silverstein & Basler to be worked out.

Books Recommended:

1. Organic chemistry – Morrison & Boyd-11th edition along with the study guide.
2. Spectroscopic methods of identification of organic compounds – Silverstein and Balaster
3. Organic spectroscopy – William kemp
4. Instrumental methods of analysis – John Dyer.
5. Structure elucidation by modern NMR, a work book – Duddeck, Detrich and Toth
6. Solving problems with NMR spectroscopy-Atta-Ur-Rahman and Muhammad Iqubal Choudhary.

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Paper 4: Screening methods in Pharmacology

Principles and techniques involved in the Pharmacological screening of:

1. Analgesic, anti-inflammatory, antipyretic and antiulcer drugs.
2. Antidiabetic and cardiotonic, antiarrhythmic and antihypertensive drugs.
3. Hepatoprotective and immunomodulatory drugs.
4. a) Screening for free radical scavenging and anti-oxidant activities.
   b) Enzyme inhibition studies – Inhibition of COX-1, COX-2 and 5-LOX
5. a) Screening of cytotoxicity
   b) Screening for antimicrobial activity
   c) Acute toxicity studies
6. Statistical analysis of data, methods of precision, accuracy, fiducial limits, regression analysis, standard error, tests for significance – chisquare test, students T test, ANOVA. Important of tests of significance in pharmaceutical/biological experiments.

Books recommended:

1. Screening methods in pharmacology – Robert A. Turner.
2. Drug Evaluation – Vogel.
3. Evaluation of Drug Activities – Lawrence and Bachrach.
4. Methods in Pharmacology – Swarbrick.
5. Pharmacopoeias.

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Semester – 1

Paper 1: Advanced Organic Chemistry – 1 Practicals

Some of the following experiments to be taught.

1. Basic Techniques:

a) Calibration of thermometer and finding melting point, mixed melting point and boiling point.

b) Purification and drying of organic solvents

c) Crystallization

d) Distillation, Fractional Distillation, Distillation under reduced pressure

2. Separation and identification of organic compounds from binary mixtures: Solid-solid, solid-liquid and liquid-liquid – atleast one mixture of each category to be done.

3. Synthesis of some of the following heterocyclic compounds:

a) Quinoline b) benzimidazole/derivative c) flavone/chromone d) indole/derivative e) phenothiazine f) oxazole/oxazolone g) benzoxazole h) 3,5 dimethylisoxazole

4. Some of the following reactions:

1. Beckmann rearrangement 2) Fries rearrangement 3) Acetylation, methylation 4) Metal/acid reductions 5) Oppenauer oxidation 6) Friedel-Craafts alkylation & Acylation 7) Nitration using different reagents

Books Recommended:

Practical Organic Chemistry – Vogel.

Paper 2: Advanced Medicinal Chemistry -1 Practicals

1. Synthesis, purification and identification some of the following drugs.

2. a) Sulfanilmide b) Uracil c) Phenytoin d) Ibuprofen e) para-Amino salicylic acid (PAS) f) Paracetamol g) Atenolol (h) proranolol.

3. Screening for the following activities
   a) CNS – Rota rod experiment Catatonia testing
   b) Experiments on isolated tissues – Testing for anti-histaminic and anti-cholinergic activities.
   c) Local anesthetic activity.

4. Spectral analysis:
   a) Spectra to be recorded for some compounds and analyzed.
   b) Analysis of pre-recorded spectra.

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Semester – II

Paper 1: Advances Organic Chemistry – 2

1. **Strategies in organic synthesis:** Introduction; target selection; disconnection approach; functional group intervoncersions; synthons; reagents; retrosyntheis, chemioselectivity, regioselectivity; linear synthesis and concergent sysnthesis.

2. **Strategies in organic sysnthesis:** one group disconnections; two group disconnections; strategic bonds; disconnection of strategic bonds in carbocyclic and heterocyclic rings; biomimetic approach; retro mass spectral fragmentation – case studies of (+) Disparlure, retronecine and longifoline.

3. **Chiral drug synthesis:** Introduction to chiral drugs; importance of stereochemistry in drug action; concepts of eutomer; distomer and eudesmic ratio, stereospecific and stereoselective synthesis; synthesis of chiral drugs like ibuprofen, propranolol, ramipril, levofloxacin.

4. **Modern synthetic methods:**
   a)Green Synthesis: Inttroduction; Green reagents; green catalysts; ionic solvents; phase transfer catalysis in green synthesis; application of phase transfer catalysts in green synthesis of heterocyclic compounds: Williamson's synthesis, Wittig reaction.
   b) Microwave assisted synthesis: Introduction; microwave reactions in water (Hofmann elimination, hydrolysis and oxidation); microwave reactions in organic solvents; solid state reactions; advantages of microwave technique.

5. **Six-membered heterocyclic ring compounds with one heteroatom:** Pyridines: nomenclature; physical and spectroscopic properties; tautomerism; synthetic methods; chemical reactions – with acids, electrophilic and nucleophilic substitution, Diels-Alder reactions, quaternization, reaction with oxidizing and reducing agents; hetaryne formation; ring opening reactions; reactions with free radicals; photochemical reactions; the Claisen rearrangement; derivatives of pyridine – alkyl and aryl pryidinesl halopyridines, aminopyridines, pyridine N-oxide, hydroxypyridines, pyridine aldhydes and ketones.

6. **Synthesis of Heterocyclic compounds:** Two methods of synthesis of the following heterocylic compounds or their derivatives; a) quinolines b) isoquinolines c) indoles d) pridazines e) pyrimidines f) pyrazines g) thiazoles h) thiazines h) imidazoles i) benzimidazoles j) oxazoles

Books recommended:

- Organic synthesis-new techniques – VK Ahluwalia & Renu Agarwal
- Top Drugs and Top Synthetic routes – John Saunder
- Theory and Practice of Green Chemistry – Paul T Anastas and John C.Warner.
- New Trends in Green Chemistry – VK Ahluwalia & M Kidwai
- Chiro Technology – Roger A. Sheldon

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- Heterocylcic Chemistry – Raj K Bansal
- Heterocyclic Chemistry – Thomas L. Gilchrist
- Heterocyclic Chemistry – JA Joule, K Mills & GF Smith
- Organic Chemistry of Synthetic drugs – Lednicer.

Semester – II

Paper 2: Advanced Medicinal Chemistry – 2

1. **Psychopharmacological agents:** Biochemical basis of mental disorders; abnormal protein factors; endogenous amines and related substances; faulty energy metabolism; genetic disorders and nutritional disorders; phenothiazines – chemistry; synthesis. Screening methods; pharmacological actions; SAR; mechanism of action; uses; toxicity; ring analogues of phenothiazines; fluorobutyrophenones; Development of atypical antipsychotics cloyepire synthesis of chlorpromazine, prochlorperazine, fluphenazine, haloperidol.

2. **Anxiolytics, sedatives and hypnotics:** Benzodiazepines and related compounds; barbiturates; other classes; mechanism of acition, SAR; uses and toxicity Synthesis of Chlordiazepoxide, diazepam, alprazolam, Phenobarbital, meprobamate.

3. **Antidepressants:** MAO inhibitors; tricylic antidepressants; SAR; mechanism of action; uses; toxicity other classes like: selective serotonin reuptake inhibitors, selective 5-HT and NE reuptake inhibitors; selective serotoninergic reuptake inhibitors and 5-HT_{2A} antagonists; 5-HT_{1A} agonists and partial agonists and α2-antagonists. Syntheis of tranycypromine, amitriptyline, fluoxetine, buspirone.

4. **Antiepileptics & CNS stimulants:**
   a) Antiepileptics: Screening methods; classification of epilepsies; symptoms; drugs used; classification; structural feactuers common to drugs; SAR; mechanism of action; toxicity and uses; synthesis of diphenylhydantion, carbamazepine, sodium valproate.
   b) CMS stimulants: an account of the drugs with CNS stimulant activity; structures and uses.

5. **Diuretics:** anatomy and physiology of nephron; classification of diuretics based on site of action; carbonic anhydrase inhibitors; thiazide and thiazide like diuretics; loop and potassium sparing diuretics; miscellanous diuretics emerging developments in the use of diuretics to treat hypertension and congestive heart failure.

6. **A Study of:** a) Anthihyperlipidemic agents
   b) phosphodiesterase inhibitors
   c) Quinolone antibacterial agents.

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Books Recommended:

1. Wilson and Gisvold's text book of pharmaceutical organic medicinal chemistry.
2. Foye's principles of medicinal chemistry.
3. Burger's text book of medicinal chemistry
4. Organic chemistry of synthetic drugs – Lednicer.

Paper 3: Chemistry of Natural Products:

1. **Alkaloids :**
   a) **Alkaloids of opium:** Structure of morphine; peripheral groups; SAR; relative potencies; development of morphine analogues; opioid receptors endorphins and enkephalins; antitussives; anti-diarrhoeals; morphine antagonists;
   b) **Alkaloids of ergot:** historical background; classification; structures; semi-synthetic derivatives; therapeutic uses; toxicity.
   c) **Source, structure, mechanism of action, use and toxicity of:** quinine, quinidine, atropine, hyoscyamine, hyoscine, reserpine, papaverine.

2. **Anticancer agents of natural origin:**
   a) **Alkaloids of Vinca rosea:** Vincristine & Vinblastine – Structures and SAR; Semisynthetic derivatives; Mechanism of Action; Uses and Toxicity.
   b) Sources and structures of podophyllotoxin, taxol and camptothecin; semisynthetic derivatives; mechanism of action; uses and toxicity.
   c) **Anticancer antibiotics:** Source; structures; description of the structural features; mechanism of action; SAR and uses of the following antibiotics; dactinomycin; daunorubicin; doxorubicin; their daunomycinol; adriamycinol; their semi-synthetic derivatives- 4'-deoxy and 4' epidoxorubicins; noglamycin and menogaril; mithramycin; mitomycins; streptozocin.
   d) Anticancer agents from marine organisms – bryostatin, dolastatin etc.

3. **Steroids:**
   a) Nomenclature; stereochemistry; numbering; new insights on steroid receptors; chemical and physical properties of steroids; changes to modify pharmacokinetic properties of steroids.
   b) Sources and structures of cholesterol, ergosterol, stigmasterol and diosgenin. History of development of steroid industry. Marker's synthesis.
   c) Steroidal anti-inflammatory agents; structures; SAR; uses and toxicity.

4. **Steroidal Hormonal Drugs:**
   a) Steroidal antifertility agents: estrogens; pregnane progestins; development of 19-norandrostanes; structures; mechanism of actions; regimen; toxicity.
   b) Anabolic Steroids: rationale for development; structures; uses; limitations.

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c) Steroids in the treatment of cancers; estrogens; antiestrogens; aromatase inhibitors; progestins; progestin antagonists; androgens and anabolic steroids; antiandrogens; 5 α-reductase inhibitors; gonadotropin inhibitors, glucocorticoids.

5. **Cephalosporins:** Historical background; classification; structures; numbering the ring system; nomenclature; degradation; spectrum of activity; SAR; β-lactamase resistance; antipseudomonal cephalosporins; mechanism of action; uses; toxicity; development of new cephalosporins – recent advances; prodrugs in cephalosporins; pencillins Vs cephalsosporins – a comparative account of the structural features and biological activity; β-lactamase inhibitors; mechanism of β-lactamase inhibition; monobactams.

6. **Structure elucidation:** of the following compounds by spectroscopic techniques like UV, IR, MS, NMR (^{1}H, ^{13}C), including 2D-NMR.
   i) Carvone, citral; menthol
   ii) Luteolin; kaempferol
   iii) Luteolin-7-O-glucoside
   iv) Nicotine; papaverine
   v) Estrone; progesterone

Note: In teaching unit – 6 the exact shift values need not be given. It is sufficient if the student is taught how many peaks appear for the compound in the NMR and approximately, in which region, how the 2D-NMR spectra like DEPT look like; which protons interact to give the COSY; and how the long range spectra will help to confirm the structure.

Books Recommended:

1. Wilson and Gisvold's text book of pharmaceutical organic medicinal chemistry.
2. Foye's principles of medicinal chemistry.
3. Burger's medicinal chemistry and drug discovery.

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Paper 4: Chromatographic separation technology

Theory and instrumentation of the following techniques for the separation of organic compounds.

1. TLC and HPTLC
2. Coloumns chromatography (open) and its modifications like flash, vacuum liquid and medium pressure chromatographies, Gel Permeation technique.
3. HPLC
4. GLC
5. Electrophoresis (Gel and Paper)
6. A brief account of:
    a) Paper chromatography
    b) Super Critical chromatography
    c) Chiral Separations
    d) Circular counter current chromatography (CCCC)
    e) Ion Exchange methods

Note: Emphasis should be on

a) The various column materials used in these techniques.
b) The detectors in the case of techniques like HPLC, HPTLC and GLC.
c) The relative advantages and limitations of the techniques.

Books recommended:

1. Instrumental methods of analysis – Willard, Merritt, Dean and Settle.
2. Instrumental methods of chemical analysis – Gurudeep R. Chatwal and Sham K. Anand.
3. TLC – Egon Stahl.
4. TLC – Kirchner.

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Semester – II

Paper 1: Chemisty of Natural Products – Practicals

1. Isolation and purification of some of the following natural products.
    a) Piperine from black pepper
    b) Strychnine and Brucine from Strychnos nuxvomica seeds
    c) Caffeine from Tea Powder
    d) Curcumin from Turmeric
    e) Bixin from Bixa orellana seeds
    f) Diosgenin from Diascoria tubers
    g) Sennosides from Senna leaves
    h) Embelin from Emblica ribes fruits
2. The use of column, flash and vacuum liquid chrmatographics for isolating some of the above mentioned phytoconstituents.
3. Identification of alkaloids in mixture by TLC.
4. Preparative TLC for separation and isolation
5. Identification of phytoconstituents like alkaloids, steroids, flavanoids etc in plant extracts by TLC.
6. Separation (of sugars/amino acids) by paper chromatography.
7. Separation of compounds by HPLC
8. Analysis of recorded spectra of some simple organic compounds.
9. Tests to detect alkaloids, steroids, flavanoids and their glycosides.

Books Recommended:

1. Natural products, a laboratory guide – Rephael Ikan.
2. Laboratory hand book for the fraction of natural extracts – Peter J. Houghton & Amala Raman.
3. An Atlas of TLC – H. Wagner.

Paper 2: Advanced Medicinal Chemistry – 2 Practicals

1. Synthesis, purification and identification of some of the following drugs;
    a) Dapsone b) Benzocaine c) Hydralazine d) Imipramine e) Sufadiazine

2. Synthesis using microwave oven: one experiment to be conducted

3. Screening for the following activities:
    a) Analgesic activity b) Anti inflammatory activity c) Acute toxicity studies
    d) Antibacterial and antifungal activity e) Free radical scavenging and anti-oxidant activities

4. Spectral analysis
    a) Spectra to be recorded for some compounds and analyzed.
    b) Analysis of pre-recorded spectra

5. Impurity profiling for one or two samples.

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