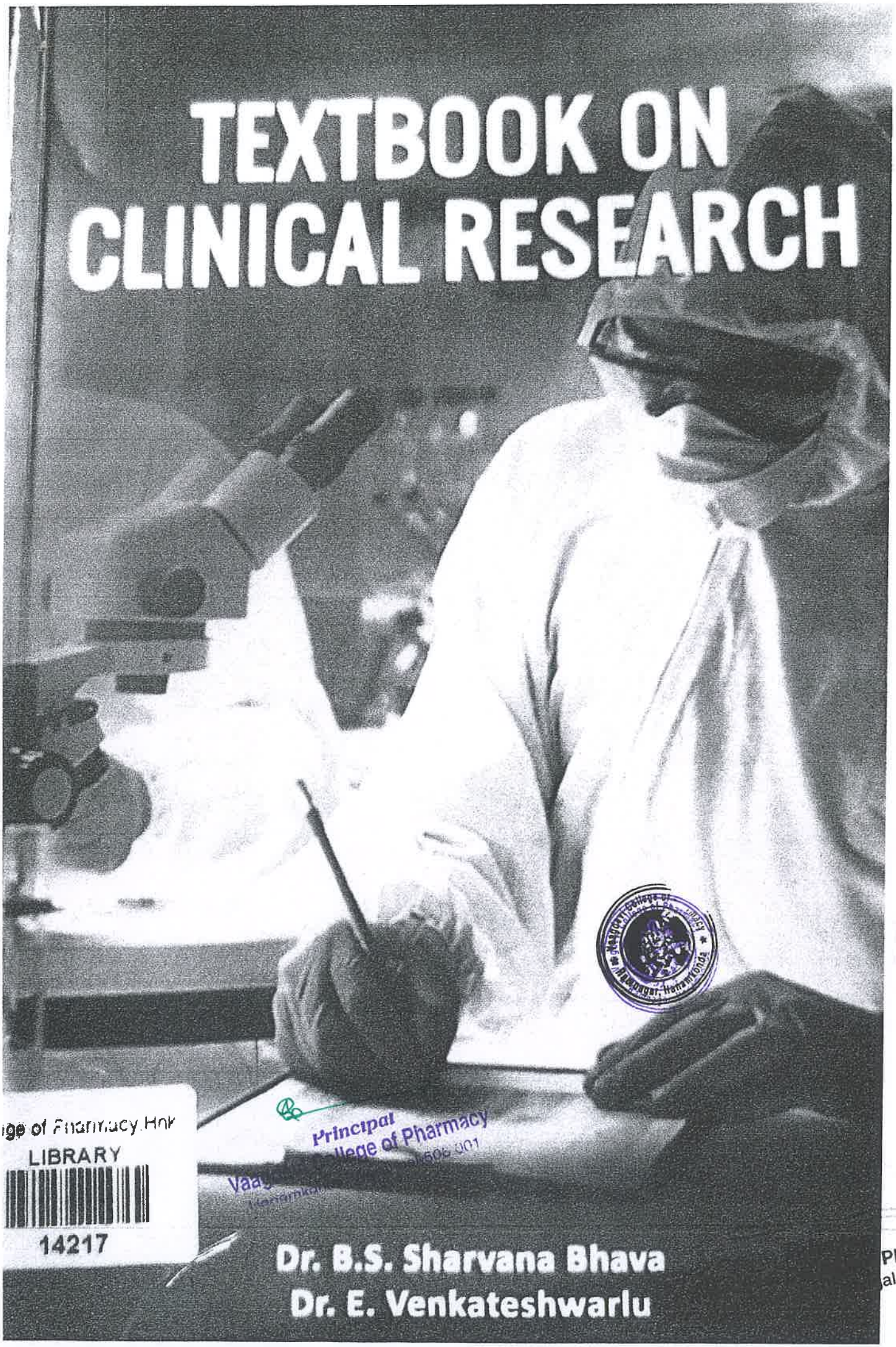
TEXTBOOK ON CLINICAL RESEARCH



Dr. B.S. Sharvana Bhava
Dr. E. Venkateshwarlu

CHAPTER–1

DEFINITIONS IN CLINICAL RESEARCH

DR. B.S.SHARVANA BHAVA *M. Pharm., Ph.D.*
DR. E. VENKATESHWARLU *M. Pharm., Ph.D.*

Act

The Act means Drugs & Cosmetics Act 1940 (23 of 1940) and the Rules made there under. As applicable in clinical research.

Adverse Drug Reaction (ADR)

- WHO defines ADR as "a response which is noxious and unintended, and occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.
- In clinical trials, an untoward medical occurrence seemingly caused by overdosing, abuse / dependence and interactions with other medicinal products is also considered as an ADR.

Audit

A methodical check of the review, completed by people not directly involved of clinical research like:

- Study related activities to determine steadiness with the Protocol
- Study data to ensure that there are no contradictions on Research Files.
- The audit should also compare data on the Source Documents with the interim or final report. It should also aim to find out if practices were employed in the development of data that would impair their validity.

CHAPTER–2

DRUG DEVELOPMENT PROCESS

DR. B.S.SHARVANA BHAVA

M.Pharm., Ph.D.

DRUG DISCOVERY AND DEVELOPMENT:

It is the mission of pharmaceutical research companies to take the path of understanding a disease to bring a safe and effective new treatment to patients. Scientists work together to know the basic causes of disease at the level of genes, proteins and cells. Out of this understanding emerge "targets," which potential new drugs might be able to affect researchers work to:

Validate these targets,

- ✓ Discover the right molecule (potential drug) to interact with the target chosen,
- ✓ Test the new compound in the lab and clinic for safety and efficacy and
- ✓ Gain approval and get the new drug-into the hands of doctors and patients.

This whole process takes an average of 10-15 years.

- For the first time in history, scientists are beginning to understand the inner engineering of human diseases at the molecular level. Recent advances in genomics, proteomics and computational power present new ways to understand illness.
- The task of discovering and developing safe and effective drugs is even more promising as our knowledge of disease

CHAPTER–3

CLINICAL TRIALS

DR. E. VENKATESHWARLU

M.Pharm., Ph.D.

Clinical research is a branch of healthcare science that determines the safety and effectiveness (efficacy) of medications, devices, diagnostic products and treatment regimens intended for human use. These may be used for prevention, treatment, diagnosis or for relieving symptoms of a disease.

Clinical trials are a subset of research that examines novel diagnostic procedures and therapeutic approaches to determine how they affect patient outcomes. Clinical trials are involve volunteers testing a variety of medical interventions such as medications, cells, biological products, surgical interventions, radiography, medical devices, behavioural therapy and preventive care .

The NIH defines a clinical trial as a prospective biomedical or behavioural research study of human subjects that is designed to answer specific questions about biomedical or behavioural interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).

Clinical trials are carefully designed, reviewed and completed, and need to be approved before they can start. People of all ages can take part in clinical trials, including children. The main objective is to study the safety and efficacy of an investigational medicinal product.

Clinical trial is a study intended to discover or verify the clinical, pharmacological and/ or other pharma codynamic effects

CHAPTER–4

POST-MARKETING SURVEILLANCE

DR. E. VENKATESHWARLU

M.Pharm., Ph.D.

POST-MARKETING SURVEILLANCE/ PHARMA COVIGILANCE

Definition: Post-marketing surveillance monitors the safety of pharmaceutical drugs / medical devices after it has been released into the market.

Post-marketing surveillance obtains information about a product after it has been approved for public use. This phase is so named because it is carried out after the drug is released in the market for therapeutic use.

It is mainly to detect rare but significant adverse effects.

Once the drug enters the market, it will be utilized by many more patients having other co-morbidity and co-existing diseases in addition to the disease for which the drug is indicated and licensed.

- No fixed duration/Patient population
- Starts immediately after the marketing
- Report all ADRS
- Help to detect
- Rare ADRs
- Drug interaction
- Also, new uses for drugs/sometimes called Phase V

CHAPTER–5

ABBREVIATED NEW DRUG APPLICATION (ANDA)

Dr. S. Pavani

An ANDA is the Submitted to regulatory bodies to obtain the approval to market a generic drug product. Once approved, an applicant may manufacture and market the generic drug product as a low cost alternative.

Generic drug applications are "abbreviated" because they are generally not required to include preclinical & clinical data instead. should demonstrate that their product is bio equivalent to innovator.

Comparison between NDA & ANDA

Brand Name Drug	Generic Drug
NDA requirements	ANDA requirements
Chemistry manufacturing	Chemistry manufacturing
1. Controls 2. Labeling 3. Testing 4. Animal studies 5. Clinical studies 6. Bioavailability	1. Controls 2. Labeling 3. Testing 4. Bioequivalence

1. PRODUCT MANUFACTURE:- Large-scale manufacture.

- It takes place at an early stage in the development process.

CHAPTER–6

GOOD CLINICAL PRACTICE - ICH-GCP GUIDELINES

DR. B.S.SHARVANA BHAVA

M.Pharm., Ph.D.

ICH -GCP Guidelines

The main challenge across all countries worldwide still appears to be protecting human subjects and ensuring that trials are conducted according to good clinical practices. [GCP]

Certainly, we have many universal standards and ethical principles or codes guiding clinical trials - the Nuremberg Code, Council for International Organizations of Medical Services (CIOMS), the Declaration of Helsinki, National Institutes of Health (NIH) Policy, the National Research Act, the Belmont Report and the International Conference on Harmonization (ICH) - GCP Guidelines. However, a major issue remains the training of all clinical researchers in GCP. It is very important to ensure, not only the satisfactory knowledge of GCP, but also the willingness to comply with the above-mentioned principles/ codes. This will provide assurance that the rights, safety and wellbeing of subjects are protected and that the trails data are credible.

The introduction of ICH Guidelines for GCP in 1966 defines GCP as "an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects".

ICH places primary importance on both the ethics and science of clinical research. The ICH was established as a joint regulatory/industry project to improve, through harmonization, the

CHAPTER–7

CENTRAL DRUGS STANDARD CONTROL ORGANISATION (CDSCO) GUIDELINES

DR. E. VENKATESHWARLU

M.Pharm., Ph.D.

CDSCO PRINCIPLES

Clinical research which involves human volunteers must be performed in compliance with the principles mentioned as per the Declaration of Helsinki and must respect 3 minimum postulates viz., Respect for individuals, justice and beneficence and no maleficence as proposed by " Ethical guidelines for Biomedical Research on Human Subjects" (ICMR) which guarantees the enhanced protection for the participants

A. Essentiality Principle :

Benefits of human beings, ecological and environmental well being of planet must be kept in mind while designing a protocol to bringing a new drug into the market. The essentiality of bringing a molecule should out weigh the risks and should necessitate the researcher for its use.

1. Informed consent, voluntary Participation and community approval

Participants of the clinical trial are appraised for their acceptance after informed consent, voluntariness, knowledge about the risks involved in trial and the retention of the right to withdraw from the work in anytime due to any consequences is impressive principle.

CHAPTER–8

CHALLENGES IN THE IMPLEMENTATION OF GUIDELINES

DR. B.S.SHARVANA BHAVA

M.Pharm., Ph.D.

Being a signatory of GATT/TRIPS, India is being looked upon as a favourable destination for conducting global clinical trials. India offers unique advantages that include lower drug development cost, abundance of patients with genetic, wide spectrum of disease, trained medical professionals, proficiency in English language.

The ICH-GCP is a harmonised standard that protects the rights, safety and welfare of human subjects, minimizes human exposure to investigation products, improves quality of data, speeds up marketing of new drugs and decreases the cost to sponsors and to the public.

- GCP is defined as a standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials or studies.
- GCP compliance provides public assurance of protecting the rights safety and well-being of the human subjects involved in the research are protected.

However, there are certain challenges in the implementation of GCP guidelines.

They include:

1. GCP trained professional

CHAPTER–9

ETHICAL PRINCIPLES IN CLINICAL RESEARCH

DR. B.S.SHARVANA BHAVA

M.Pharm., Ph.D.

Although clinical research has resulted in significant bene for society, it continues to pose profound ethical questions.

ETHICAL ATTENTION TO CLINICAL RESEARCH

Benefit to the Individual:

- Research was done sporadically since long.
- Little basis for a distinction between experimentation therapy as most therapy was experimental.
- Experimental therapy was used to try to benefit ill pati but often contributed to or caused morbidity or mortality.
- Fraud and abuse were minimized through peer censorshi there were no specific codes of ethics, laws, or regulat governing the conduct of research.
- According Food, Drug, and Cosmetic Act in 1938 there need for information on safety and efficacy of a drug be it's available in market.

Benefit to Society

- Just before World War II large amounts of both public private money were devoted to research
- Research became increasingly centralized, coordin standardized in method, and valued.

Vaagdevi College of Pharmacy Ramnagar, Hanamkonda

Principal
Vaagdevi College of Pharmacy
Warangal-506 001

CHAPTER–10

INSTITUTIONAL REVIEW BOARD/ INDEPENDENT ETHICS COMMITTEE (IRB/IEC)

DR. C. SRINIVAS REDDY

M.Pharm., Ph.D.

As per CDSCO, Ethics committee consists of medical, scientific, non-medical and non-scientific members, whose responsibility is to assure the protection of the rights, safety and well-being of human subjects involved in a clinical trial.

Composition:

1) The IRB/IEC must contain members who collectively have the qualifications and experience to review and assess the science, medical aspects, and ethics of the proposed trial.

2) The IRB/IEC must contain:

   a) Atleast five members

   b) Atleast one member with primary area of interest in non-scientific area.

   c) Atleast one member who doesn't belong to the institution/trial site.

Functions:

1) The IRB/IEC should perform its role according to written operating procedures.

2) It should maintain written records of its activities and minutes of meetings.

CHAPTER–11

OVERVIEW OF REGULATORY ENVIRONMENT IN USA, EUROPE & INDIA

DR. S. PAVANI
M.Pharm., Ph.D.

DRUG APPROVAL PROCESS IN DIFFERENT NATIONS

Drug approval is the procedure in which an individual, group, sponsor, or innovator obtains permission to introduce a drug into the market. A drug approval process typically consists of several stages.

* Application to conduct clinical trials.
* Conducting clinical trials.
* Application to marketing authorization of drugs and Post-marketing studies.

Every country has its own regulatory authority, which is responsible to enforce the rules and regulations and issues the guide lines to regulate the marketing of the drugs. The new drug approval is conducted in the two phases.

a. The first phase is of clinical trials.
b. The second phase for marketing authorization of drug.

Prior to submitting an application to the relevant authority of the concerned country for the conduct of clinical trials non-clinical trials studies of a drug are done to ensure its safety and efficacy. There after the clinical trials can be conducted (Phase- I to Phase -). These studies are performed to ensure the efficacy, safety and optimizing the dose of the drug in human beings. After completion

CHAPTER–12

ROLES AND RESPONSIBILITIES OF CLINICAL TRIAL PERSONNEL AS PER ICH/GCP

DR. B.S.SHARVANA BHAVA *M.Pharm., Ph.D.,*

DR. E. VENKATESHWARLU *M.Pharm., Ph.D.,*

1) SPONSOR

Sponsor is an individual, company, institution or organization which takes responsibility for the initiation, management and/or financing of a clinical trial. FDA regulations, Indian GCP Guidelines and ICH Guidelines defines various roles and responsibilities of a sponsor as follows:

1. Selection of investigator & trial site

a. It is the responsibility of sponsor to select well qualified, trained, and experienced investigator(s) for the conduct of trial. The selected investigator should be based at the institutions/hospitals having sufficient resources to properly conduct the trial.

b. It's the sponsor duty to organize a coordinating committee and/or to select coordinating investigator(s) if required

c. A copy of the Protocol and an up-to date investigator's Brochure should be provided to the investigator(s)/ institution(s) to provide them the sufficient time to review the documents.

2. MOU's / Agreements

The sponsor should enter in an agreement with the investigator's/ institution for the conduct of the trial according to

CHAPTER–13

PROTOCOL FOR CLINICAL TRIAL

DR. B.S.SHARVANA BHAVA
M.Pharm., Ph.D.

Protocol:

A Well structured study relies principally on a thoroughly reviewed, well organized and complete protocol.

COMPONENTS OF PROTOCOL

General information:

Protocol title, protocol identifying number and date. All amendments should bear amendment number and date(s)

Name, address & contact numbers of the sponsor and the monitor / CRO

Name and title of the persons authorized to sign the protocol and the protocol amendments for the sponsor.

Name, title, address and contact numbers of the sponsor's medical expert for the study.

Name(s), title(s), address(es) and contact numbers of the investigator(s) who is / are responsible for conducting the study, along with their consent letter(s).

Name, title, address, and telephone number(s) of the qualified physician (or dentist, if applicable), who is responsible for all trial-site related medical (or dental) decisions (if other than investigator).

Name(s), address(es) and contact numbers of the institution(s) - clinical laboratories, and / or other medical and

CHAPTER–14

DESIGNING OF CLINICAL STUDY DOCUMENT - CRF

DR. B.S.SHARVANA BHAVA
M.Pharm., Ph.D.

Case Report Form (CRF):

- Tool designed for collection and recording information of the patients.
- Analysis as well as reporting of trial –based on data collected
- Standard and uniform form-Accuracy and complete information.
- CRF-paper based/ electronic format.
- Electronic format-Direct data entry.
- Difference b/w protocol and CRF.
- CRF-design-easy to record and review by investigator, monitor, data manager.

CHARACTERISTICS:

- Clear, systemic, simple, quick and unambiguous.
- Complete Information as per protocol.
- Collect precise Information.
- Eligibility criteria for patient.
- Minimum uncertainties.
- Entry verification.
- Help in creating and design clean database without queries.

CHAPTER–15

DESIGNING OF CLINICAL STUDY DOCUMENT-PIC

DR. E. VENKATESHWARLU
M.Pharm., Ph.D.

Participant Identification Centres (PIC)

What is a PIC?

A PIC is: Any organization in charge of locating and alerting potential participants to a research being conducted by another organization

A PIC is not: A research site in charge of the following evaluation of prospective participants, as well as their recruitment and informed consent into the study. Responsible for carrying out the study procedures outlined in the research protocol. (e.g blood test or X-ray to determine if a participant is eligible for randomisation or informed consent).

Advantages of PICs:

- PICs help in identifying a bigger volunteers through various hospital organizations and minimize the cost and identification, recruitment methods.

PICs will verify whether -

- The study has received ethical approval and is pertinent to the patient population.
- The relevant regulatory/necessary governmental authorizations are present.
- Concerns about data security and privacy have been handled.

CHAPTER–16

INFORMED CONSENT PROCESS

DR.B.S.SHARVANA BHAVA *M.Pharm., Ph.D.*

DR.E.VENKATESHWARLU *M.Pharm., Ph.D.*

When securing and recording informed consent, researchers must adhere to relevant regulatory standards, as well as Good Clinical Practice (GCP) guidelines, and uphold ethical principles rooted in the Declaration of Helsinki.

Before commencing the trial, the investigator must obtain written approval or a favourable opinion from the Institutional Review Board (IRB) or Independent Ethics Committee (IEC) regarding the informed consent form and any accompanying written materials intended for subjects.

Any significant new information that could affect a subject's decision to consent should prompt revisions to the informed consent form and related materials. These revised documents must be approved by the IRB/IEC before implementation.

Subjects or their legally acceptable representatives should be promptly notified of any pertinent new information that may impact their willingness to continue participating in the trial, with all such communications being documented.

In no circumstance should the investigator or trial staff coerce or unduly influence a subject to participate or remain in the trial. Both oral and written information provided to subjects, including the informed consent form, should not contain language that suggests waiving any legal rights or releasing the investigator, institution, sponsor, or their agents from liability for negligence.

CHAPTER–17

DATA MANAGEMENT AND ITS COMPONENTS

DR.B.S.SHARVANA BHAVA *M.Pharm., Ph.D.*

DR. A. MAKARANDH, *Pharm. D.*

Clinical trials serve the purpose of assessing the efficacy and safety of drugs or devices, relying on the quality of collected data, which is subsequently submitted for review. This data holds significant value for pharmaceutical and biotech companies, as its quality directly influences the probability of drug or device approval for marketing. Therefore, effective data management is paramount in ensuring trial success. Implementing appropriate data management methods enhances data quality, leading to the establishment of clinical data management as a distinct subject.

The process of drug development encompasses various stages, including formulation, toxicology, and clinical trials. Clinical trials, in particular, consist of several stages, though they may overlap. A study commences with a defined objective, which is then translated into a protocol. Subsequently, sites are identified, and trial management ensues. The actual data management process commences with data collection, marking a crucial phase in the trial progression.

HISTORY OF CLINICAL DATA MANAGEMENT

Clinical data management (CDM) has evolved significantly over time, transitioning from a simple data entry task to a multifaceted process aimed at delivering clean and usable data in a timely manner. This evolution is evident in the shift towards ensuring that databases are fit for use and that data is clean and ready for locking.

CHAPTER–18

SAFETY MONITORING IN CLINICAL TRIALS

DR. B.S.SHARVANA BHAVA *M.Pharm., Ph.D.*

DR. A. MAKARANDH *Pharm. D,*

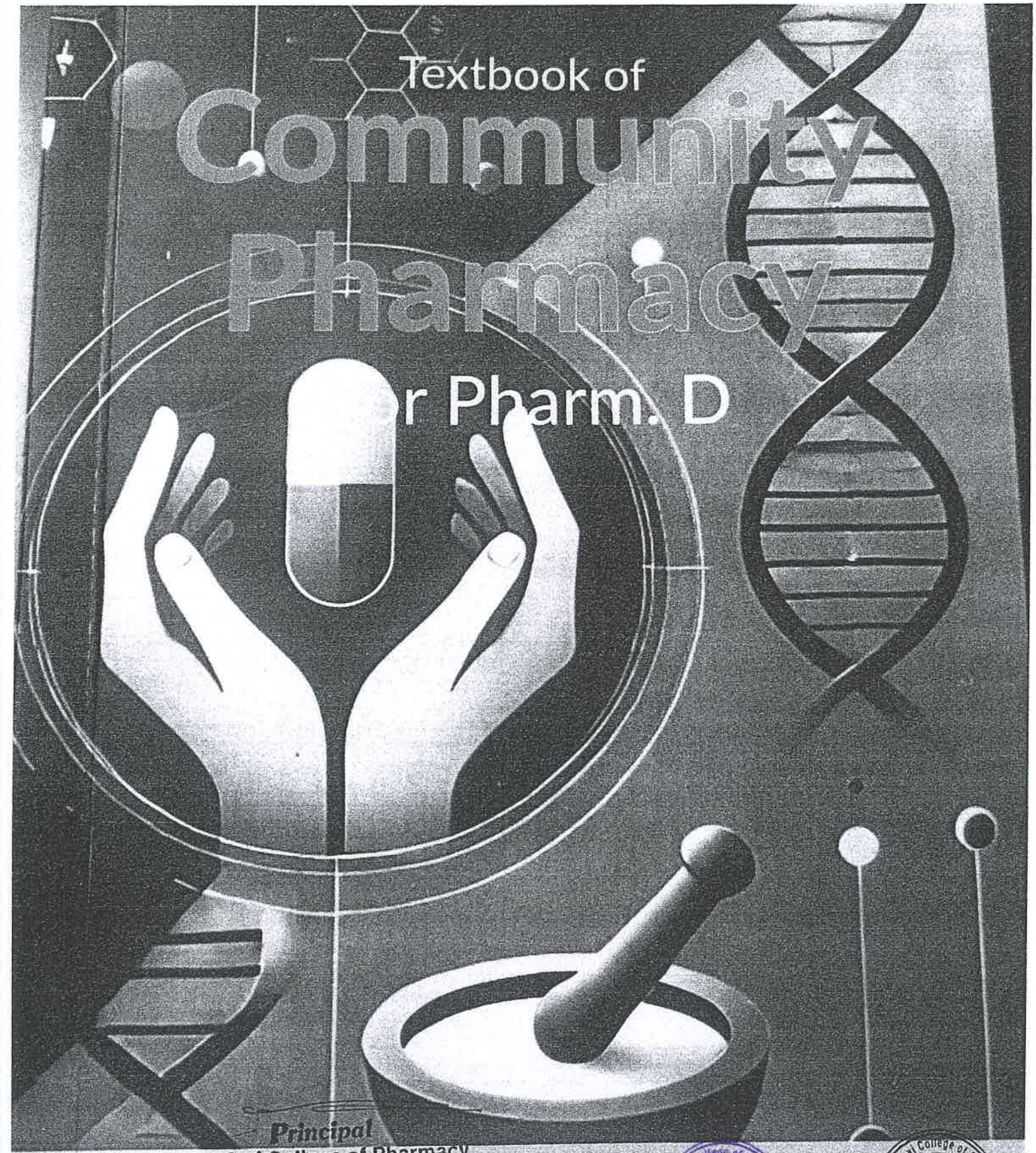
- Medical advancements are due to the continuous research through clinical trials. The progress in conduct and design of a trial proves these advances in medicine. NIH (National Institutes of Health) policy explains that the safety of trial participants in primary concern and there must be a system to ensure the safety of volunteers. Establishment of DSMBs (Drug Safety Monitoring Board) plays an important role in ensuring participants safety and assess the studies validity in a scientific way.

Safety Monitoring :

- Safety monitoring of participants in a clinical trial is conducted by an independent physician with other clinical trial expert team.
- This can be achieved by review of ADRs, soon after they occur and their management with timely follow up through resolution.

GCP guidelines :

- An international ethical and scientific standard for design, conduct, record and report clinical trials using human subjects was given by GCP guidelines.
- Assurance about the credibility and accuracy of results and also the rights, confidentiality and integrity of the trial subjects are protected by following the GCP guidelines.



Textbook of Community Pharmacy

r Pharm. D

r. Challa Srinivas Reddy
Dr B .S. Sharvana Bhava
Dr. Santhi Sree Vemulapalli

Dr. B.S. Sharvana Bhava is a forerunner in the field of Clinical Research with a Ph.D. in Pharmaceutical Sciences and an M.Sc. in Psychology, he brings a unique blend of expertise to his role as Professor & Head, Department of Clinical Pharmacy and Pharm.D. at Vaagdevi College of Pharmacy, Ramnagar, Hanamkonda. With over 13 years of teaching experience, Dr. Sharvana has handled various subjects such as Human Anatomy and Physiology, Pharmacology, Pharmacotherapeutics I, II & III, Clinical Pharmacy, Research Methodology, Clinical Toxicology and Clinical Research and this has been instrumental in shaping the careers of countless students and has provided guidance and mentorship to numerous M. Pharmacy and Pharm.D. students, aiding them in achieving excellence in their respective fields through their project works. His dedication to this field is evident through his extensive contributions. Dr. Sharvana has authored over 50 publications in various prestigious peer-reviewed journals, both Nationally and Internationally. His research spans from Pre-clinical to Clinical evaluations, showcasing his depth of knowledge and commitment to advancing Pharmaceutical Research. Beyond his academic achievements, Dr. Sharvana is known for his dynamic and inspirational presence in the Pharmaceutical Research community. His passion for his work is infectious, motivating both students and colleagues to strive for excellence in their endeavours. In this book, Dr. B.S. Sharvana bhava invites you to explore the topics of Clinical Research through his expert insights and experiences.

Dr. E. Venkateshwarlu, a prominent figure in the field of Pharmacology & Clinical Research. Currently serving as Professor & Head of the Pharmacology Department at Vaagdevi College of Pharmacy, Ramnagar, Hanamkonda with an impressive 19 years of teaching experience. His commitment to research is evident through his extensive publication record, boasting over 60 research papers in various esteemed National and International journals. As the Member Secretary of the Institutional Animal Ethics Committee (IAEC), he has played a pivotal role in overseeing pre-clinical evaluations, conducting meetings, and ensuring ethical standards are met. Dr. Venkateshwarlu earned his Ph.D. in Pharmaceutical Sciences from Acharya Nagarjuna University in 2015, further solidifying his expertise in the field. His areas of specialization include Advanced Pharmacology, Advances in pre-clinical evaluation, Hospital Pharmacy, Clinical Toxicology, and Clinical Trials. Not only is Dr. Venkateshwarlu a prolific researcher, but he is also deeply invested in nurturing the next generation of scholars. He has mentored numerous M. Pharmacy and Pharm.D. students in their project works, guiding them towards excellence in their respective fields. In this book, Dr. Venkateshwarlu brings his wealth of knowledge and experience to the table, offering invaluable insights and expertise to fellow researchers and practitioners in the field of clinical research.

Principal
College of Pha
Warangal-506 00

Vaagdevi College of Pharmacy
Ramnagar, Hanamkonda

Principal
Vaagdevi College of Pharmacy
Hanamkonda, Warangal-506 001

indispensable guide for pharmacy students, educators, and professionals aiming to excel in the dynamic field of community pharmacy. This textbook seamlessly blends theoretical rigor with practical insights, offering a comprehensive exploration of the principles and practices that define the role of the community pharmacist.

Key features include:

- Therapy
- Decision-Making
- Counselling
- Promotion

Each chapter is meticulously structured to provide deep understanding of knowledge alongside real-world applications, ensuring that readers are well-prepared to deliver high-quality, patient-centered care.

Focus on Community Health: Special emphasis is placed on the pharmacist's crucial role in enhancing community health. From managing minor ailments to educating patients on medication adherence and navigating complex ethical issues, this book provides clear guidance and practical strategies that reflect the latest advancements in pharmaceutical science.

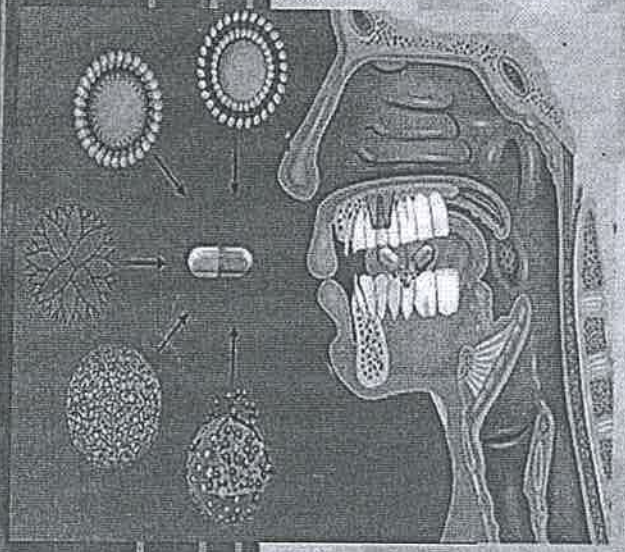
A Must-Have Resource: Aligned with the Pharm.D curriculum, "Textbook of Community Pharmacy: For Pharm.D" is more than just a textbook—it's a valuable resource for making a meaningful impact on patient care. Whether you are a student or a practicing pharmacist, this book will be your trusted companion throughout your education and professional journey.

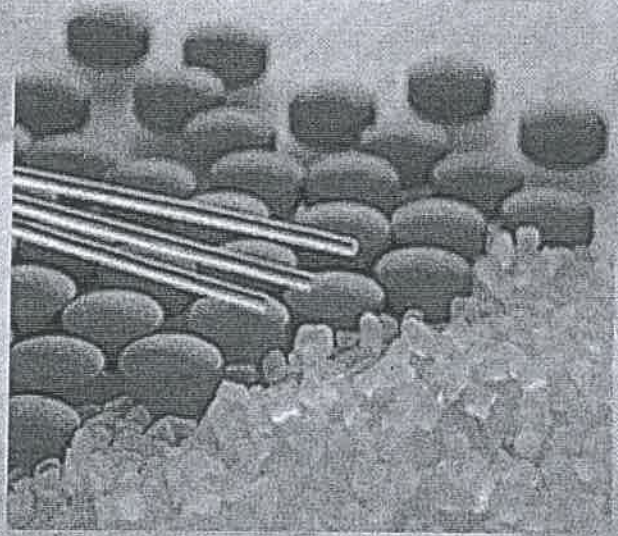
Price Rs 469.00
979-889544360-6

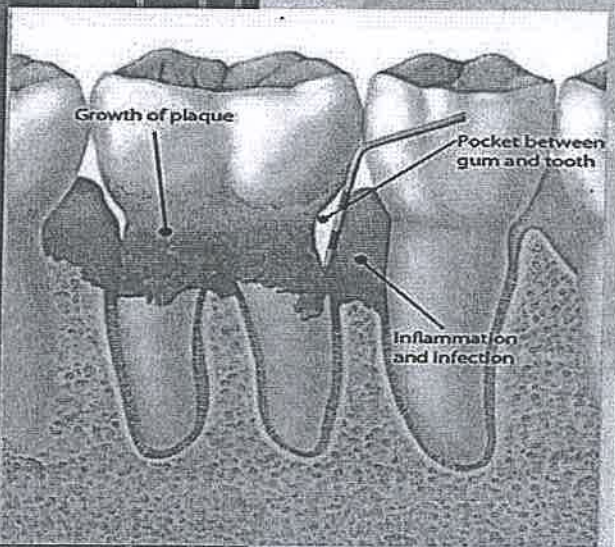
9 798895 443606

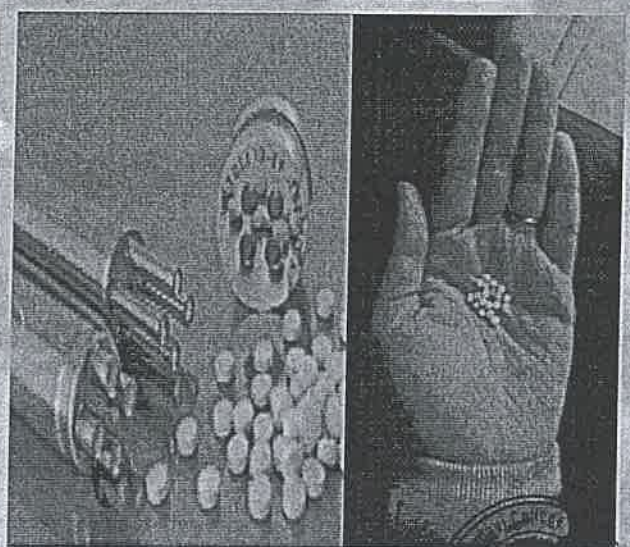
Advances in Drug Delivery

Volume V









Editors
Y Madhusudan Rao
Y. Shravan Kumar

Pharma Med PRESS
An Imprint of BSP Books Pvt. Ltd.

1

Dental Inserts

Prof. Y. Shravan Kumar[1,2], Dr. Pavani Sriram[1], S. Harika[1], M. Mounika[1] and Prof. Y. Madhusudan Rao[3]

[1]Vaagdevi College of Pharmacy, Raamnagar, Hanamkonda

[2]Magnificent cosmo cosmeceuticals

[3]Magnificent cosmo cosmoceuticals

Dental Inserts

Insert means the dosage form to place or introduce into the body. The insert mainly used for dental cavity are called as dental insert.

The mouth is a naturally dirty field, besides its high content of microflora, its high moisture content (96%) and appropriate temperature (37 °C) increases the incidence of bacteria. (Dolan, Matulka, & Burdock, 2010). Development of bacteria is a concern for dentist as it is associated with failure of dental procedures especially dental implants. Anaerobic gram positive cocci, and anaerobic gram negative rods are amongst the most common strains involved in dental surgery infections. The use of prophylactic antibiotics to combat these strains becomes a general practice in dental implants and procedures. High dose of systemic antibiotics are used to achieve adequate concentrations in the blood to prevent the growth and dissemination of bacteria at the site of implant surgery. The adverse effects associated with the use of systemic antibiotics makes it unappealing, hence the local application of an antibiotic medicated implant will be advantageous. Main advantages of dental inserts are localized action, reduced frequency of administration, reduced side effects and sustained action. Some of the disadvantages of dental inserts are it requires technical person for the administration and drug loss through saliva.

2

Cubosomes

Prof. Y. Shravan Kumar[1] and T. Rajani[1]

[1]Vaagdevi College of Pharmacy, Raamnagar, Hanamkonda

Introduction

Drug Delivery

Drug delivery refers to approaches, formulations, technologies, and systems for transporting a pharmaceutical compound in the body. It may involve scientific site-targeting within the body, or it might involve facilitating systemic pharmacokinetics concerned with both quantity and duration of drug presence. Drug delivery is often approached via a drug's chemical formulation, but it may also involve medical devices or drug-device combination products. Drug delivery is a concept heavily integrated with dosage form and route of administration.

Drug delivery technologies modify drug release profile, absorption, distribution and elimination for the benefit of improving product efficacy and safety, as well as patient convenience and compliance.

Novel Drug Delivery

Nanoparticles are of current interest because of an emerging understanding of their possible effects on human health and environmental sustainability, and owing to the increasing output of man-made nanoparticles into the environment. Nanoparticles are used in many different applications and created by many different processes. Their measurement and characterization pose interesting analytical challenges.

6

Solid Dispersion

Dr. Y. Shravan Kumar[1], Dr. A. Bhargavilatha[2], and Dr. Y. Vamshi Vishnu[3]

Prof and HOD Pharmaceutical DoPt [1]Vaagdevi College of Pharmacy, Ramnagar, Hanamkonda

HOD, Drug Regulatory affairs [2]Nethaji Institute of Pharmaceutical Sciences

[3]Director Anjali College of Pharmacy and Sciences, Etmadur, Agra, U.P.,

Director Magnificent cosmo cosmoceuticals

Introduction

The oral route of drug administration is the most common and preferred method of delivery due to convenience and easy of digestion. From a patient's perspective, swallowing a dosage form is a comfortable and a familiar means of taking medication.

Although the oral route of administration is preferred, for many drugs it can be a problematic and inefficient mode of delivery for a number of reasons. Limited drug absorption resulting in poor bioavailability is paramount amongst the potential problems that can be encountered when delivering an active agent via oral route. Drug absorption form the gastrointestinal (GI) tract can be limited by a variety of factors with the most significant contributors being poor solubility in intestinal fluids before it can permeate the embranes of the GI tract to reach systemic circulation. Therefore, a drug with poor membrane permeability will typically exhibit permeation rate limited absorption. Hence, two areas of pharmaceuticgents include (1) enhancing solubility and dissolution rate of al research that focus on improving the oral bioavailability of active apoorly water soluble and (2) enhancing permeability of poor permeable drugs. This article focus on the former, in particular, the use of solid

7

Chewing Gum as Drug Delivery

Prof. Y. Shravan Kumar[1,3], Dr. Rajitha Koppula[2], Prof. Y. Madhusudhan Rao[2,3]

[1]Vaagdevi College of Pharmacy, Raamnagar, Hanamkonda

[2]Vaagdevi Institute of Pharmaceutical Sciences

[3]Magnificent cosmo cosmoceuticals

Introduction

Medicated chewing gum is a solid, single-dosage preparation that has been to be chewed and not swallowed; chewing gum contains one or more active ingredients that are released by chewing. A medicated chewing gum is intended to be chewed for certain period of time, required to deliver the dose, after which the remaining mass is discarded.

During the chewing process the drug contained in the product is released from the mass into saliva and could be absorbed through the oral mucosa or swallowed reaching stomach for gastro-intestinal absorption.

Chewing gum can be used as a convenient modified release drug delivery system.

Medicated chewing gums are currently available for pain relief, smoking cessation, travel illness, freshening of breath, obesity. (Savaliya Prithik *et al.*, 2011)

There are two absorption pathways which are possible to introduce the active ingredient into the systemic circulation giving rise to a systemic effect. Drug absorbed directly via the buccal membrane avoids metabolism in the GIT and the first-pass effect of the liver, it might

8

Sublingual Drug Delivery

Prof. Y. Shravan Kumar[1], Dr. A. Bhargavi latha[2], Prof. Y. Vamshi Vishnu[3], Prof. Y. Madhusudan Rao[4]

[1]Vaagdevi College of Pharmacy, Raamnagar, Hanamkonda

[2]Nethaji Institute of Pharmaceutical Sciences

[3]Anjali College of Pharmacy and Sciences, Etmadur, Agra, U.P., Magnificent cosmo cosmoceuticals

[4]Magnificent cosmo cosmeceuticals

Introduction

Oral administration is the most widely used route because of ease of ingestion, pain avoidance, and most importantly patient compliance. Solid oral delivery systems do not require sterile conditions and are therefore less expensive to manufacture. One important drawback of solid dosage forms is the difficulty in swallowing (dysphasia) or chewing in some patient's particularly pediatric and geriatric patients. The problem of swallowing is common phenomenon in geriatric patient due to fear of choking, hand tremors, dysphasia and in children's due to under developed muscular and nervous systems.

The unique environment of the oral cavity offers its potential as a site for drug delivery, because rich blood supply and direct access to systemic circulation, the oral mucosal route is suitable for drugs which are susceptible to acid hydrolysis in the stomach or which are extensively metabolized in the liver. The continuous secretion of saliva results in rapid removal of released drug and this may desire that the oral cavity be restricted to the delivery of drugs, which have a short systemic circulation. The mucin film, which exists on the surface of the oral mucosa may provide an opportunity to retain a drug delivery system in

9

Pelletization Techniques

Prof. Y. Shravan Kumar[1], B. Gavaskar[2] and Prof. Y. Bhargavi Latha[3], Prof. Y. Madhusudhan Rao[4]

[1]Vaagdevi College of Pharmacy, Raamnagar, Hanamkonda

[2]SB Organics Ltd, Unit –II, Sanga Reddy, Telangana

[3]Nethaji Institute of Pharmaceutical Sciences

[4]Vaagdevi Institute of Pharmaceutical Sciences, Bollikunta, Hanamkonda

Introduction

In the past few eras, pharmaceutical invention and research on drug delivery has reformed astonishingly and even greater changes are anticipated in the forthcoming future to supplement desirable therapeutic intents with minimizing side effects. The key purpose of the drug therapy is to accomplish a curative and healing effect. For the motive, to improve and make advances in the delivery of pharmaceutical compound(s) and therapy, the area is being extensively researched and a marked growth have seen till date and development is still on going.

Drugs are being consumed to enrich health and expand life. To acquire the assumed therapeutic response and to be absorbed as well as transported to the site of action at the right time, an appropriate amount of the active drug is needed. The rate of input drug quantity can be regulated based on various drug delivery systems and routes of administration to maintain the effective level of essential concentration for as long as necessary.

Drug delivery is an approach of transporting a medicinal compound of required dose into the body to safely accomplish the desired therapeutic effect in animals/ humans. Drug delivery systems are the technologies that facilitate the ingestion of engineered therapeutic agent(s) into the