## PHARMACEUTICS

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## SEMESTER II

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# PHARMACOLOGY

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- **MPT 2986**
PHARMACEUTICS

1st SEMESTER

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

(MPT 1061)

Scope
This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives
After completion of course student is able to know,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY

60 HOURS


b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy


11 Hrs

2  NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

11 Hrs
4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:  
a) Paper chromatography  
b) Thin Layer chromatography  
c) Ion exchange chromatography  
d) Column chromatography  
e) Gas chromatography  
f) High Performance Liquid chromatography  
g) Affinity chromatography  
5 a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:  
a) Paper electrophoresis  
b) Gel electrophoresis  
c) Capillary electrophoresis  
d) Zone electrophoresis  
e) Moving boundary electrophoresis  
f) Isoelectric focusing  
b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg’s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of Xray diffraction. 
6 Immunological assays : RIA (Radio immuno assay), ELISA, Bioluminescence assays. 5 Hrs

REFERENCES
DRUG DELIVERY SYSTEMS
(MPT 1062)

SCOPE
This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

OBJECTIVES
Upon completion of the course, student shall be able to understand
- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering systems.
- The formulation and evaluation of Novel drug delivery systems.

THEORY 60 Hrs
   Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy. 10 Hrs
4. Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers. 06 Hrs
5 Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation. 10 Hrs
6 Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules. 08 Hrs
7 Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines. 06 Hrs

REFERENCES
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York, Chichester/Weinheim
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

JOURNALS
1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

MODERN PHARMACEUTICS
(MPT 1063)

SCOPE
Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

OBJECTIVES
Upon completion of the course, student shall be able to understand
The elements of preformulation studies.

The Active Pharmaceutical Ingredients and Generic drug Product development

Industrial Management and GMP Considerations.

Optimization Techniques & Pilot Plant Scale Up Techniques

Stability Testing, sterilization process & packaging of dosage forms.

**THEORY**

60 HRS

1. a. Preformation Concepts – Drug Excipient interactions - different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation. 10 Hr

b. Optimization techniques in Pharmaceutical Formulation:

Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation 10 Hr

2 Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities. 10 Hr

3 cGMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management. 10 Hr

4 Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility. 10 Hr

5 Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation , Chi square test, students T-test , ANOVA test. 10 Hr

REFERENCES
1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
8. Physical Pharmacy; By Alfred Martin
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
13. How to practice GMPs; By P.P. Sharma. Vandhana Publications, Agra.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

**REGULATORY AFFAIRS**
(MPT 1064)

**Scope**
Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
OBJECTIVES:
Upon completion of the course, it is expected that the students will be able to understand
- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance’s and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilence and process of monitoring in clinical trials.

THEORY 60 Hrs
1. a. Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction, Hatch-Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION), drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. 12 Hrs
b. Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs 12 Hrs
2 CMC, post approval regulatory affairs. Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries. 12 Hrs
3 Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB). 12 Hrs
4 Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials. 12 Hrs

REFERENCES
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm

PHARMACEUTICS PRACTICALS - I
(MPT 1960)
1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Mucoadhesive tablets.
12. Formulation and evaluation of transdermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and Peppas plot and determine similarity factors.
2nd SEMESTER

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)
(MPT 2061)

SCOPE
This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

OBJECTIVES
Upon completion of the course student shall be able to understand
- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of NTDS
- The formulation and evaluation of novel drug delivery systems.

THEORY 60 Hrs
1. Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery. 12 Hrs
4. Pulmonary Drug Delivery Systems: Aerosols, propellents, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation. 12 Hrs

REFERENCES

**ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS**

**(MPT 2062)**

**SCOPE**

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students” to clarify the concepts.

**OBJECTIVES**

Upon completion of this course it is expected that students will be able understand,

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutical studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

**THEORY**

60 Hrs

1. Drug Absorption from the Gastrointestinal Tract:

Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH–partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of invivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and
the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex. 12 Hrs


3 Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of kmax and vmax. Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters. 12 Hrs

4 Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution. 12 Hrs

5 Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, oligonucleotides, Vaccines (immunotherapy), Gene therapies. 12 Hrs

REFERENCES
2. Biopharmaceautics and Pharmacokinetics, A. Treatise, D. M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book

COMPUTER AIDED DRUG DEVELOPMENT
(MPT 2063)

SCOPE
This course is designed to impart knowledge and skills necessary for computer applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

**OBJECTIVES**

Upon completion of this course it is expected that students will be able to understand,

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics (CFD)

**THEORY**


   12 Hrs

b. Quality-by-Design In Pharmaceutical Development:
Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.

   12 Hrs


   12 Hrs

3 Computer-aided formulation development:: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers
Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis 12 Hrs

4 a. Computer-aided biopharmaceutical characterization:
Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro in vivo correlation, Biowaiver considerations

c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems 12 Hrs

5 Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions. 12 Hrs

REFERENCES

COSMETICS AND COSMECEUTICALS
(MPT 2064)

SCOPE
This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

OBJECTIVES
Upon completion of the course, the students shall be able to understand

☐ Key ingredients used in cosmetics and cosmeceuticals.
☐ Key building blocks for various formulations.
☐ Current technologies in the market
☐ Various key ingredients and basic science to develop cosmetics and cosmeceuticals
Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

**THEORY**

60 Hrs


2 Cosmetics - Biological aspects: Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm. 12 Hrs


Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane. 12 Hrs

4 Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor., dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations. 12 Hrs

5 Herbal Cosmetics: Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics. 12 Hrs

REFERENCES


3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.

PHARMACEUTICS PRACTICALS - II
(MPT 2960)

1. To study the effect of temperature change, non solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products/brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline R software
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling Of Drug Disposition
17. To develop Clinical Data Collection manual
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff
PHARMACOLOGY

1st SEMESTER

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

(MPT 1081)

SCOPE
This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives
After completion of course student is able to know about,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY 60 Hrs

1. UV-Visible spectroscopy: Introduction, Theory, Laws,

2 NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy. 10 Hrs

4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:  
j) Thin Layer chromatography  
k) High Performance Thin Layer Chromatography  
l) Ion exchange chromatography  
m) Column chromatography  
n) Gas chromatography  
o) High Performance Liquid chromatography  
p) Ultra High Performance Liquid chromatography  
q) Affinity chromatography  
r) Gel Chromatography  

5 Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:  
a) Paper electrophoresis  
b) Gel electrophoresis  
c) Capillary electrophoresis  
d) Zone electrophoresis  
e) Moving boundary electrophoresis  
f) Iso electric focusing  
Crystallography: Production of X rays, Different X ray methods, Bragg,s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.  

Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications.  
Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA).
TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications. 10 Hrs

REFERENCES

ADVANCED PHARMACOLOGY - I
(MPT 1082)

SCOPE
The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved

OBJECTIVES
Upon completion of the course the student shall be able to:
- Discuss the pathophysiology and pharmacotherapy of certain diseases
- Explain the mechanism of drug actions at cellular and molecular level
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases
THEORY  

1. General Pharmacology
   b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects.  

2. Neurotransmission
   a. General aspects and steps involved in neurotransmission.
   b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters - Adrenaline and Acetyl choline).
   c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters - histamine, serotonin, dopamine, GABA, glutamate and glycine).
   d. Non adrenergic non cholinergic transmission (NANC). Co-transmission

Systemic Pharmacology
A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems

Autonomic Pharmacology
Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

3. Central nervous system Pharmacology: General and local anesthetics, Sedatives and hypnotics, drugs used to treat anxiety. Depression, psychosis, mania, epilepsy, neurodegenerative diseases. Narcotic and non-narcotic analgesics.  

4. Cardiovascular Pharmacology
Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants, anticoagulants, fibrinolytics and antiplatelet drugs.  

5. Autocoid Pharmacology
The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.
REFERENCES
1. The Pharmacological Basis of Therapeutics, Goodman and Gillman.,s
3. Basic and Clinical Pharmacology by B.G Katzung
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C. Yu.
7. Avery Drug Treatment
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING
METHODS - I
(MPL 1083)

SCOPE
This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the
student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes

Objectives

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

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
- Describe the various newer screening methods involved in the drug discovery process
- Appreciate and correlate the preclinical data to humans

**THEORY** 60 Hrs

1. Laboratory Animals

Common laboratory animals: Description, handling and applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications Anaesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals Good laboratory practice.

Bioassay-Principle, scope and limitations and methods 12 Hrs


4 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic


REFERENCES
1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
5. Fundamentals of experimental Pharmacology by M.N.Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)
CELLULAR AND MOLECULAR PHARMACOLOGY
(MPT 1084)

SCOPE:
The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

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

- Explain the receptor signal transduction processes.
- Explain the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques as applicable for pharmacology

THEORY

1. Cell biology
Structure and functions of cell and its organelles Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing

2. Cell signaling
Intercellular and intracellular signaling pathways. Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.
Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol.
Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

3. Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene therapy Basic principles of
recombinant DNA technology. Restriction enzymes, various types of vectors. Applications of recombinant DNA technology. Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy. 12 Hrs

4 Pharmacogenomics

5 a. Cell culture techniques
Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays. Principles and applications of flow cytometry. 12 Hrs

b. Bio-similars

REFERENCES:
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach ) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M. Ausuvel et al. 219

PHARMACOLOGICAL PRACTICAL - I
(MPT 1985)
1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

Handling of laboratory animals.
1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogens and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry’s in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
17. DNA fragmentation assay by agarose gel electrophoresis.
18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

REFERENCES
1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman,
7. Vogel„s Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L. Mille
9. Basic Cell Culture (Practical Approach ) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
2nd SEMESTER
ADVANCED PHARMACOLOGY - II
(MPT 2081)

SCOPE
The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved

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

☐ Explain the mechanism of drug actions at cellular and molecular level
☐ Discuss the Pathophysiology and pharmacotherapy of certain diseases
☐ Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

THEORY 60 Hrs

1. Endocrine Pharmacology
Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones. Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids. Drugs affecting calcium regulation 12 Hrs

2 Chemotherapy
Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as β-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs. 12 Hrs

3 Chemotherapy
Drugs used in Protozoal Infections, Drugs used in the treatment of Helminthiasis, Chemotherapy of cancer

Immunopharmacology
Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immunosuppressants and Immunostimulants 12 Hrs

4 GIT Pharmacology
Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.

Chronopharmacology

Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer 12 Hrs

5 Free radicals Pharmacology

Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant ; Recent Advances in Treatment: Alzheimer’s disease, Parkinson’s disease, Cancer, Diabetes mellitus 12 Hrs

REFERENCES

1. The Pharmacological basis of therapeutics- Goodman and Gill man,
3. Basic and Clinical Pharmacology by B.G -Katzung
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. KD.Tripathi. Essentials of Medical Pharmacology
PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING

METHODS-II

(MPT 2082)

SCOPE:
This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug &
new chemical entity. This knowledge will make the student competent in regulatory
toxicological evaluation.

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

☐ Explain the various types of toxicity studies.
☐ Appreciate the importance of ethical and regulatory requirements for toxicity studies.
☐ Demonstrate the practical skills required to conduct the preclinical toxicity studies.

THEORY

60 Hrs

1. Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive)
Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y, OECD
principles of Good laboratory practice (GLP), History, concept and its importance in drug
development
12 Hrs

2 Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines.
Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item
characterization- importance and methods in regulatory toxicology studies
12 Hrs

3 Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive
studies (segment I and segment III), teratogenecity studies (segment II) Genotoxicity studies
(Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies) In vivo
carcinogenicity studies
12 Hrs

4 IND enabling studies (IND studies)- Definition of IND, importance of IND, industry
perspective, list of studies needed for IND submission. Safety pharmacology studies- origin,
concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety
pharmacology, HERG assay. Tier2- GI, renal and other studies .
12 Hrs

5 Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance
and applications of toxicokinetic studies. Alternative methods to animal toxicity testing. 12 Hrs

REFERENCES
3. Drugs from discovery to approval by Rick NG.
5. OECD test guidelines.

PRINCIPLES OF DRUG DISCOVERY
(MPT 2083)

SCOPE:
The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

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

☐ Explain the various stages of drug discovery.
☐ Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery.
☐ Explain various targets for drug discovery.
☐ Explain various lead seeking method and lead optimization.
☐ Appreciate the importance of the role of computer aided drug design in drug discovery.

THEORY

60 Hrs

1. An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery. Target Discovery and validation - Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation. 12 Hrs
2 Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification.

Protein structure
Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction 12 Hrs

3 Rational Drug Design
Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches, Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening, 12 Hrs

4 Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them. 12 Hrs

5 QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design 12 Hrs

REFERENCES
2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
CLINICAL RESEARCH AND PHARMACOVIGILANCE
(MPT 2084)

SCOPE:
This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

OBJECTIVES:
Upon completion of the course, the student shall be able to,
- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

THEORY 60 Hrs
1. Regulatory Perspectives of Clinical Trials:
2 Clinical Trials: Types and Design, Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management

3 Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring- Safety Monitoring in CT

5 Methods, ADR reporting and tools used in Pharmacovigilance

7 Pharmacoeconomics, safety pharmacology

REFERENCES


1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine the strength of unknown sample by interpolation bioassay by using suitable tissue preparation.
5. To determine the strength of unknown sample by bracketing bioassay by using suitable tissue preparation.
6. To determine the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations.
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial.(3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting

REFERENCES
1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.
Course of study for M. Pharm. III Semester

Common for all specialisations

<table>
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<tr>
<th>Sr.No.</th>
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<td>Discussion / Presentation (Proposal)</td>
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<td>MPT-392</td>
<td>Research Work</td>
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**SESSIONAL***

| 1.     | MPT-384     | Research Methodology and Biostatistics* | 4  |          | 100        | 4             |
| 2.     | MPT-381     | Journal club                           | 1  |          | 100        | 1             |

Total 4 31 21

*Non University Exam
UNIT-I
General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT-II
Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students “t” test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT-III
Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT-IV
CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT-V
Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.
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<td>Co-curricular Activities</td>
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**Total**
### Syllabus of M. Pharm. IV Semester

(Effective for 2018-2019 Admission Session)

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### Guidelines for Awarding Credit Points for Co-curricular Activities

(One 1 Credit & One 2 Credit Course to be chosen)

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**Note:** International Conference: Held Outside India  
International Journal: The Editorial Board outside India