



VIJAYA INSTITUTE OF PHARMACEUTICAL SCIENCES FOR WOMEN, Enikepadu, VIJAYAWADA – 521108

Permitted by Govt. of A.P; Approved by AICTE, New Delhi
Pharmacy Council of India, New Delhi & Affiliated to JNTU Kakinada
ISO 9001:2015 Certified Institution

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Program: Master of Pharmacy

Duration: 2 years

Course: Pharmaceutics

Program Specific Outcomes (PSO):

1. Impart knowledge on the novel drug delivery systems, approaches, criteria for selection of polymers and drugs and their formulation and evaluation.
2. To know various preformulating elements, industrial management and GMP considerations, Pilot Plant Scale Up Techniques, Stability testing, sterilization and packaging of dosage forms.
3. To impart knowledge and skills in generic drug development, various regulatory filings the approval process, and concept of generics across the globe.
4. To impart knowledge and skills for dose calculations, dose adjustments and apply biopharmaceutics theories in practical problem solving. The pharmacokinetic models, bioequivalence and potential clinical pharmacokinetic problem analysis
5. Skill development in Pharmaceutical research, Pharmacoinformatic, in drug development in Computational modeling, Preclinical development, clinical development, Artificial Intelligence and Robotics, and Computational fluid dynamics
6. To impart knowledge and skills necessary for cosmetics and cosmeceuticals, their safety and efficacy and current technologies in cosmetic industry
7. To gain knowledge in use of advanced instrumentation, formulation and evaluation of controlled release formulations, floating drug delivery systems, transdermal drug delivery systems, micromeritics, and mathematical simulations
8. To train the students and develop their technical skill knowledge in computer simulations, population modelings, in vitro and in vivo studies
9. To create a talent pool by involving students in research projects and to make students undertake research projects under faculty guidance for publication

10. To foster ambitious desire among students to undertake higher studies and career growth

Course: Pharmaceutical Analysis

1. Able to perform qualitative and quantitative analysis of drugs in different matrices by various spectroscopic, electro-analytical and chromatographic techniques
2. Able to perform stability studies, impurity profiling and metabolite profiling of drugs by hyphenated analytical techniques
3. Thorough knowledge about quality control, quality assurance of pharmaceuticals and regulatory guidelines

Course: Pharmacology

1. Ability to understand, establish the core mechanisms of action of drugs
2. Strengthen the basis, knowledge, criteria for selection of appropriate drug in different disease conditions based on their uses, side effects, etc.
3. Ability to estimate the kinetic profile of a drug in a patient body i.e., Pharmacotherapeutic drug monitoring
4. Ability to carry out in vivo & in vitro experiments and provides strong base for planning of future research in drug discovery and clinical trails

PHARMACEUTICS (MPH)

SEMESTER - I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

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

1. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV- Visible spectroscopy. 11 Hrs
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
c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
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

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| 3 | Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass 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 | 11
Hrs |
| 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) Iso electric 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 X- ray diffraction. | 11
Hrs

5 Hrs |
| 6 | Immunological assays : RIA (Radio immuno assay), ELISA, Bioluminescence assays. | |

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

DRUG DELIVERY SYSTEMS (MPH 102T)

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 system
- ▮ The formulation and evaluation of Novel drug delivery systems..

THEORY

60 Hrs

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| 1. | Sustained Release(SR) and Controlled Release (CR) formulations: Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application 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 |
| 2 | Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals. | 10
Hrs |
| 3 | Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations. | 10
Hrs

06
Hrs |
| 4 | Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers. | |

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

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

JOURNALS

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

MODERN PHARMACEUTICS (MPH 103T)

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

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| 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
Hrs |
| | 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
Hrs |
| 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
Hrs |
| 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
Hrs |

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| 4 | Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility. | 10
Hrs |
| 5 | Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckel plots, Similarity factors – f ₂ and f ₁ , Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test. | 10
Hrs |

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol. 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred Martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H. Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P. Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
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 (MPH 104T)

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

- || Toknow the approval process of
- || To know the chemistry, manufacturing controls and their regulatory importance
- || To learn the documentation requirements for
- || To learn the importance and

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
- || Pharmacovigilance 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

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| 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

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer, Marcel Dekker series, Vol. 143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol. 185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol. 190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. <https://www.tga.gov.au/tga-basics>

PHARMACEUTICS PRACTICAL - I

(MPH 105PA)

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 carry out preformulation studies of tablets.
8. To study the effect of compressional force on tablets disintegration time.
9. To study Micromeritic properties of powders and granulation.

PHARMACEUTICS PRACTICAL - II

(MPH 105PB)

1. To study the effect of particle size on dissolution of a tablet.
2. To study the effect of binders on dissolution of a tablet.
3. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.
4. To perform In-vitro dissolution profile of CR/ SR marketed formulation
5. Formulation and evaluation of sustained release matrix tablets
6. Formulation and evaluation osmotically controlled DDS
7. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
8. Formulation and evaluation of Muco adhesive tablets.
9. Formulation and evaluation of trans dermal patches.

SEMESTER - II
**MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY &
TARGETED DDS) (NTDS)**
(MPH 201T)

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
2. Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation.	12 Hrs
3. Micro Capsules / Micro Spheres: Types, preparation and evaluation , Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.	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
5. Nucleic acid based therapeutic delivery system : Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and nonviral gene transfer). Liposomal gene delivery systems. Biodistribution and Pharmacokinetics. knowledge of therapeutic antisense molecules and aptamers as drugs of future.	12 Hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. S.P. Vyas and R.K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

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 biopharmaceutic 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 in vivo 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
2. Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing, performance of drug products. In vitro-in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product. 12 Hrs
3. Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extravascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis-Menten equation, estimation of k_{max} and v_{max} . 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

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| 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

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pamarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

COMPUTER AIDED DRUG DEVELOPMENT (MPH 203T)

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

60 Hrs

1. a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling 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.
2. Computational Modeling Of Drug Disposition: Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter. 12 Hrs

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| 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 Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis | 12
Hrs |
| 4 | <p>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</p> <p>b. Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.</p> <p>c. Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems</p> | 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

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James G. Boylan, Marcel Dekker Inc, New York, 1996.

FORMULATION DEVELOPMENT OF PHARMACEUTICAL AND COSMETIC PRODUCTS (MPH204T)

Scope

This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D.

Objectives

On completion of this course it is expected that students will be able to understand-
The scheduled activities in a Pharmaceutical firm.

The pre formulation studies of pilot batches of pharmaceutical industry. The significance of dissolution and product stability

THEORY

60 Hrs

1. Preformulation Studies:

12 Hrs

Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

2. Formulation Additives:

12 Hrs

Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments – factorial design for product and process development.

3. Solubility & Dissolution:

12 Hrs

Importance, experimental determination, phase- solubility analysis, pH-solubility profile, solubility techniques to improve solubility and utilization of analytical methods – cosolvency, salt formation, complexation, solid dispersion, micellar solubilization and hydrotrophy. Theories and mechanisms of dissolution, in-vitro dissolution testing models – sink and non-sink. Factor influencing dissolution and intrinsic dissolution studies. Dissolution test apparatus – designs, dissolution testing for conventional and controlled release products. Data handling and correction factor. Biorelevant media, in-vitro and in-vivo correlations, levels of correlations.

4. Product Stability:

12 Hrs

Degradation kinetics, mechanisms, stability testing of drugs and pharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies, interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment. Stability protocols, reports and ICH guidelines.

5. Cosmetics:

12 Hrs

Formulation, Evaluation and packaging of the following cosmetic products: Dentrifices like tooth powders, pastes and gels. ManIcure preparations like nail polish, lipsticks, eye lashes, Baby care products, Moisturizing cream, vanishing cream, cold cream, shampoo, Soaps and syndetbars

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice of Industrial Pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5 ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nded., CBS Publishers & distributors, New Delhi, 2005.
4. Conners KA. A Text book of pharmaceutical analysis Wells JI. Pharmaceutical preformulation: The physicochemical properties of drug substances. Ellis Horwood Ltd., England, 1998.
5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12. Marcel Dekker Inc., New York, 1981
6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurah printer pvt. Ltd., New Delhi, 2005.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rd ed., CBS publications, New Delhi, 2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3rd ed., CBS Publishers & distributors, New Delhi, 2005.
9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer (India) Pvt. Ltd., New Delhi, 2006.
10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
11. W. Grimm - Stability testing of drug products.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd., Bangalore, 1999.
13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I & II., 4th ed., CBS Publishers & distributors, New Delhi, 2004.
13. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
14. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
15. United States Pharmacopoeia. United States Pharmacopoeial Convention, Inc, USA, 2003.
16. Encyclopaedia of Pharm. Technology, Vol I – III.
17. Wells J. I. Pharmaceutical Preformulation : The physicochemical properties of drug substances, Ellis Horwood Ltd. England, 1988.
18. Harry's Cosmeticology. 8th edition.
19. Poucher's perfume cosmetics and Soaps, 10th edition.
20. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma, 4th edition
21. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3rd edition

PHARMACEUTICS PRACTICAL - III

(MPH 205PA)

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

PHARMACEUTICS PRACTICAL - IV

(MPH 205PB)

1. DoE Using Design Expert[®] Software
2. Formulation data analysis Using Design Expert[®] Software
3. Quality-by-Design in Pharmaceutical Development
4. Computer Simulations in Pharmacokinetics and Pharmacodynamics
5. Computational Modeling Of Drug Disposition
6. To develop Clinical Data Collection manual
7. To carry out Sensitivity Analysis, and Population Modeling.
8. Development and evaluation of Creams
9. Development and evaluation of Shampoo and Toothpaste base
10. Formulation Development of Multi Vitamin Syrup
11. Use of Optimization techniques in Formulation Development of Tablets

PHARMACEUTICAL ANALYSIS (MPA)

SEMESTER - I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPA 101T)

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. a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/Derivative spectroscopy. 10 Hrs
- 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, Data Interpretation.
- c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
- d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
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
3. Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass 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:

- | | | |
|---|--|-----|
| | a. Thin Layer chromatography | |
| | b. High Performance Thin Layer Chromatography | 10 |
| | c. Ion exchange chromatography | Hrs |
| | d. Column chromatography | |
| | e. Gas chromatography | |
| | f. High Performance Liquid chromatography | |
| | g. Ultra High Performance Liquid chromatography | |
| | h. Affinity chromatography | |
| | i. Gel 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) Iso electric focusing | 10 |
| | b. X ray 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 | Hrs |
| 6 | Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. | |
| | 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

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley eastern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED PHARMACEUTICAL ANALYSIS (MPA 102T)

Scope

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradants, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

Objective

After completion of the course students shall able to know,

- ▯ Appropriate analytical skills required for the analytical method development.
- ▯ Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
- ▯ Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

THEORY

60 Hrs

1. Impurity and stability studies:

Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines

10
Hrs

Impurities in new drug products:

Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products

Impurities in residual solvents:

General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents

2. Elemental impurities:

Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis

10
Hrs

Stability testing protocols:

Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates. With practical considerations.

3	Impurity profiling and degradant characterization: Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradant characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products	10 Hrs
4	Stability testing of phytopharmaceuticals: Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity.	10 Hrs
5	Biological tests and assays of the following: a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)	10 Hrs
6	Immunoassays (IA) Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA.	10 Hrs

REFERENCES

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons, 1982.
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – PD Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, New Delhi, 1964.
8. Indian Pharmacopoeia Vol I, II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

PHARMACEUTICAL VALIDATION (MPA 103T)

Scope

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Objectives

Upon completion of the subject student shall be able to

- ▮ Explain the aspect of validation
- ▮ Carryout validation of manufacturing processes
- ▮ Apply the knowledge of validation to instruments and equipments
- ▮ Validate the manufacturing facilities

THEORY

60 Hrs

- | | | |
|----|--|-----------|
| 1. | Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.
Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re-Qualification (Maintaining status- Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments. | 12
Hrs |
| 2 | Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette. | 12
Hrs |
| 3 | Validation of Utility systems: Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen. Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP). | 12
Hrs |
| 4 | Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP. Computerized system validation: Electronic records and digital significance-21 CFR part 11 and GAMP 5. | 12
Hrs |

- 5 General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices. 12 Hrs

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Upl, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Inter Science.

FOOD ANALYSIS (MPA 104T)

Scope

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

Objectives

At completion of this course student shall be able to understand various analytical techniques in the determination of

- ▮ Food constituents
- ▮ Food additives
- ▮ Finished food products
- ▮ Pesticides in food
- ▮ And also student shall have the knowledge on food regulations and legislations

THEORY

60 Hrs

1. Carbohydrates: classification and properties of food carbohydrates, 12
General methods of analysis of food carbohydrates, Changes in food 12
carbohydrates during processing, Digestion, absorption and metabolism of Hrs
carbohydrates, Dietary fibre, Crude fibre and application of food
carbohydrates
Proteins: Chemistry and classification of amino acids and
proteins, Physico-Chemical properties of protein and their structure,
general methods of analysis of proteins and amino acids, Digestion,
absorption and metabolism of proteins.
2. Lipids: Classification, general methods of analysis, refining of fats and oils; 12
hydrogenation of vegetable oils, Determination of adulteration in fats and Hrs
oils, Various methods used for measurement of spoilage of fats and fatty
foods.
Vitamins: classification of vitamins, methods of analysis of vitamins,
Principles of microbial assay of vitamins of B-series.
3. Food additives: Introduction, analysis of Preservatives, antioxidants, 12
artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and Hrs
jelling agents.
Pigments and synthetic dyes: Natural pigments, their
occurrence and characteristic properties, permitted synthetic dyes, Non-
permitted synthetic dyes used by industries, Method of detection of natural,
permitted and non-permitted dyes.

- | | | |
|---|--|-----------|
| 4 | General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk.
Analysis of fermentation products like wine, spirits, beer and vinegar. | 12
Hrs |
| 5 | Pesticide analysis: Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorus and organochlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products.
Legislation regulations of food products with special emphasis on BIS, Agmark, FDA and US-FDA. | 12
Hrs |

REFERENCES

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food constituents – Multon, Wiley VCH.
5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

PHARMACEUTICAL ANALYSIS PRACTICAL - I (MPA 105PA)

1. Calibration of glasswares
2. Calibration of pH meter
3. Calibration of UV-Visible spectrophotometer
4. Calibration of FTIR spectrophotometer
5. Calibration of GC instrument
6. Calibration of HPLC instrument
7. Cleaning validation of any one equipment
8. Impurity profiling of drugs
9. Assay of official compounds by different titrations
10. Assay of official compounds by instrumental techniques.
11. Estimation of riboflavin/quinine sulphate by fluorimetry
12. Estimation of sodium/potassium by flame photometry
13. Quantitative determination of hydroxyl group.
14. Quantitative determination of amino group
15. Colorimetric determination of drugs by using different reagents

PHARMACEUTICAL ANALYSIS PRACTICAL - II (MPA 105PB)

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. Determination of total reducing sugar
6. Determination of proteins
7. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
8. Determination of fat content and rancidity in food products
9. Analysis of natural and synthetic colors in food
10. Determination of preservatives in food
11. Determination of pesticide residue in food products
12. Analysis of vitamin content in food products
13. Determination of density and specific gravity of foods
14. Determination of food additives

SEMESTER - II
ADVANCED INSTRUMENTAL ANALYSIS
(MPA 201T)

Scope

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, and hyphenated techniques.

Objectives

After completion of course student is able to know,

- ▮ interpretation of the NMR, Mass and IR spectra of various organic compounds
- ▮ theoretical and practical skills of the hyphenated instruments
- ▮ identification of organic compounds

THEORY

60 Hrs

1. HPLC: Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development, New developments in HPLC-role and principles of ultra, nano liquid chromatography in pharmaceutical analysis. Immobilized polysaccharide CSP's: Advancement in enantiomeric separations, revised phase Chiral method development and HILIC approaches. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC. 12 Hrs
2. Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases. 12 Hrs
Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification. High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications.
3. Super critical fluid chromatography: Principles, instrumentation, pharmaceutical applications. 12 Hrs
Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, CE characteristics, principles of CE, methods and modes of CE. General considerations and method development in CE, Crown ethers as buffer additives in capillary electrophoresis. CE-MS hyphenation

- 4 Mass spectrometry: Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, FAB and MALD, APCI, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight, FT-ICR, ion trap and Orbitrap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF; Q-IT, Q-TOF, LTQ-FT, LTQ-Orbitrap). 12 Hrs
- 5 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 with reference to ¹³CNMR: Spin spin and spin lattice relaxation phenomenon. ¹³CNMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations. 12 Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.
8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.

MODERN BIO-ANALYTICAL TECHNIQUES (MPA 202T)

Scope

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

Objectives

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

- ▮ Extraction of drugs from biological samples
- ▮ Separation of drugs from biological samples using different techniques
- ▮ Guidelines for BA/BE studies.

THEORY

60 Hrs

1. Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid - Liquid extraction and Solid phase extraction and other novel sample preparation approach. 12 Hrs
Bioanalytical method validation: USFDA and EMEA guidelines.
2. Biopharmaceutical Consideration: Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods. 12 Hrs
3. Pharmacokinetics and Toxicokinetics: Basic consideration, Drug interaction (PK-PD interactions), The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters. Microsomal assays Toxicokinetics-Toxicokinetic evaluation in preclinical studies, Importance and applications of toxicokinetic studies. LC-MS in bioactivity screening and proteomics. 12 Hrs
4. 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 applications. Principles and applications of cell viability assays (MTT assays), Principles and applications of flow cytometry. 12 Hrs

- 5 Metabolite identification: 12 Hrs
In-vitro / in-vivo approaches, protocols and sample preparation. Microsomal approaches (Rat liver microsomes (RLM) and Human liver microsomes (HLM) in Met-ID. Regulatory perspectives.
In-vitro assay of drug metabolites & drug metabolizing enzymes.

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

REFERENCES

- 1 Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, Newyork. 1995.
- 2 Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
- 3 Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.
- 4 Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
- 5 Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
- 6 Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
- 7 Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercy, USA. 2007.
- 8 Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
- 9 Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
- 10 ICH, USFDA & CDSCO Guidelines.
- 11 Palmer

QUALITY CONTROL AND QUALITY ASSURANCE (MPA 203T)

Scope

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

Objectives

At the completion of this subject it is expected that the student shall be able to know

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

THEORY

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|---|--------|
| | 60 hrs |
| 1. Concept and Evolution of Quality Control and Quality Assurance | 12 Hrs |
| Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines.
Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of nonclinical testing, control on animal house, report preparation and documentation. | |
| 2. cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines. | 12 Hrs |
| 3. Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3) | 12 Hrs |
| Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials. | |

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|----|---|-----------|
| 4. | Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data. | 12
Hrs |
| 5. | Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging. | 12
Hrs |

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – PP Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

HERBAL AND COSMETIC ANALYSIS (MPA 204T)

Scope

This course is designed to impart knowledge on analysis of herbal products. Regulatory requirements, herbal drug interaction with monographs. Performance evaluation of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

Objectives

At completion of this course student shall be able to understand

- ▮ Determination of herbal remedies and regulations
- ▮ Analysis of natural products and monographs
- ▮ Determination of Herbal drug-drug interaction
- ▮ Principles of performance evaluation of cosmetic products.

THEORY

60 Hrs

1. Herbal remedies- Toxicity and Regulations: Herbs vs Conventional drugs, Efficacy of herbal medicine products, Validation of Herbal Therapies, Pharmacodynamic and Pharmacokinetic issues. Herbal drug standardization: WHO and AYUSH guidelines. 12 Hrs

2. Adulteration and Deterioration: Introduction, types of adulteration/substitution of herbal drugs, Causes and Measure of adulteration, Sampling Procedures, Determination of Foreign Matter, DNA Finger printing techniques in identification of drugs of natural origin, heavy metals, pesticide residues, phototoxin and microbial contamination in herbal formulations. 12 Hrs
Regulatory requirements for setting herbal drug industry:
Global marketing management, Indian and international patent law as applicable herbal drugs and natural products and its protocol.

3. Testing of natural products and drugs: Effect of herbal medicine on clinical laboratory testing, Adulterant Screening using modern analytical instruments, Regulation and dispensing of herbal drugs, Stability testing of natural products, protocol. 12 Hrs

Monographs of Herbal drugs: Study of monographs of herbal drugs and comparative study in IP, USP, Ayurvedic

Pharmacopoeia, American herbal Pharmacopoeia, British herbal Pharmacopoeia, Siddha and Unani Pharmacopoeia, WHO guidelines in quality assessment of herbal drugs.

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| 4 | Herbal drug-drug interaction: WHO and AYUSH guidelines for safety monitoring of natural medicine, Spontaneous reporting schemes for bio drug adverse reactions, bio drug-drug and bio drug-food interactions with suitable examples. Challenges in monitoring the safety of herbal medicines. | 12
Hrs |
| 5 | Evaluation of cosmetic products: Determination of acid value, ester value, saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.
Indian Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau Indian Standards. | 12
Hrs |

REFERENCES

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Quality Control Methods for Medicinal Plant, WHO, Geneva
4. Pharmacognosy & Pharmacobiotechnology by Ashutosh Kar
5. Essential of Pharmacognosy by Dr.S.H.Ansari
6. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
7. Indian Standard specification, for raw materials, BIS, New Delhi.
8. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
9. Harry's Cosmeticology 8th edition
10. Suppliers catalogue on specialized cosmetic excipients
11. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
12. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition,

PHARMACEUTICAL ANALYSIS PRACTICAL - III

(MPA 205PA)

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical / Bioanalytical method validation.
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.

PHARMACEUTICAL ANALYSIS PRACTICAL - IV

(MPA 205PB)

1. In process and finished product quality control tests for tablets, capsules, parenterals and creams
2. Quality control tests for Primary and secondary packing materials
3. Assay of raw materials as per official monographs
4. Testing of related and foreign substances in drugs and raw materials
5. Preparation of Master Formula Record.
6. Preparation of Batch Manufacturing Record.
7. Quantitative analysis of rancidity in lipsticks and hair oil
8. Determination of aryl amine content and Developer in hair dye
9. Determination of foam height and SLS content of Shampoo.
10. Determination of total fatty matter in creams (Soap, skin and hair creams)
11. Determination of acid value and saponification value.
12. Determination of calcium thioglycolate in depilatories

PHARMACOLOGY (MPL)

SEMESTER - I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPL 101T)

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. | a) UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy. | 10 Hrs |
| | 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, Data Interpretation. | |
| | c) Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. | |
| | d) Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications. | |
| 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 ¹³ C NMR. Applications of NMR spectroscopy. | 10 Hrs |
| 3 | Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass 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: | |

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|----|---|-----|
| a) | Thin Layer chromatography | |
| b) | High Performance Thin Layer Chromatography | 10 |
| c) | Ion exchange chromatography | Hrs |
| d) | Column chromatography | |
| e) | Gas chromatography | |
| f) | High Performance Liquid chromatography | |
| g) | Ultra High Performance Liquid chromatography | |
| h) | Affinity chromatography | |
| i) | 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 | 10 |
| | X ray 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. | Hrs |
| 6 | Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry. | |
| | 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. | 10 |
| | 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. | Hrs |

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Ed, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED PHARMACOLOGY - I

(MPL 102T)

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

60 Hrs

1. General Pharmacology

12

- a Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding.
- 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.

Hrs

2 Neurotransmission

12

- 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

Hrs

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.	12 Hrs
4	Cardiovascular Pharmacology Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants , anticoagulants, fibrinolytics and anti- platelet drugs	12 Hrs
5	Autocoid Pharmacology The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.	12 Hrs

REFEERENCES

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's
2. Principles of Pharmacology. The Pathophysiological basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C. Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K.Srivastava published by APC Avichal Publishing Company
12. KD.Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics : Concepts and Applications – Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I

(MPL 103T)

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	12 Hrs
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	
2. Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.	12 Hrs
General principles of preclinical screening. CNS Pharmacology: behavioral and muscle coordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.	
3. Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.	12 Hrs
Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti - emetic, anti- diarrheal and laxatives.	

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| 4. | Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.
Cardiovascular Pharmacology: antihypertensives, antiarrhythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods. | 12
Hrs |
| 5. | Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.
Immunomodulators, Immunosuppressants and immunostimulants
General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin.
Limitations of animal experimentation and alternate animal experiments.
Extrapolation of in vitro data to preclinical and preclinical to humans. | 12
Hrs |

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
4. Methods in Pharmacology by Arnold Schwartz.
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.
8. Experimental Pharmacology by R.K.Goyal.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3rd Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
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 (MPL 104T)

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

60 Hrs

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

Cell cycles and its regulation.

Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis.

Necrosis and autophagy.

12

Hrs

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.

12

Hrs

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

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|----|---|-----------|
| 4. | Pharmacogenomics
Gene mapping and cloning of disease gene.
Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism
Genetic variation in drug transporters
Genetic variation in G protein coupled receptors
Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics Immunotherapeutics
Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice | 12
Hrs |
| 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
b. Biosimilars | 12
Hrs |

REFERENCES:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
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 Cheri 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 protocols in molecular biology vol I to VI edited by Frederick M. Ausuvel et la.

PHARMACOLOGICAL PRACTICAL - I (MPL 105PA)

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.

7. Various routes of drug administration.
8. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
9. Functional observation battery tests (modified Irwin test)
10. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
11. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
12. Evaluation of diuretic activity.
13. Evaluation of antiulcer activity by pylorus ligation method.
14. Oral glucose tolerance test.

PHARMACOLOGICAL PRACTICAL - II (MPL 105PB)

Handling of laboratory animals.

1. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
2. Isolation of RNA from yeast
3. Estimation of proteins by Bradford/Lowry's in biological samples.
4. Estimation of RNA/DNA by UV Spectroscopy
5. Gene amplification by PCR.
6. Protein quantification Western Blotting.
7. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
8. Cell viability assays (MTT/Trypan blue/SRB).
9. DNA fragmentation assay by agarose gel electrophoresis.
10. DNA damage study by Comet assay.
11. Apoptosis determination by fluorescent imaging studies.
12. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
13. Enzyme inhibition and induction activity
14. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
15. 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
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Douglas 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)
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd

SEMESTER – II

ADVANCED PHARMACOLOGY - II (MPL 201T)

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

60Hrs

- | | | |
|----|---|-----------|
| 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 Gilman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
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)
10. A Complete Textbook of Medical Pharmacology by Dr. S.K.Srivastava published by APC Avichal Publishing Company.
11. KD.Tripathi. Essentials of Medical Pharmacology
12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II

(MPL 202T)

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), teratogenicity 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

- 1 Hand book on GLP, Quality practices for regulated non-clinical research and development (<http://www.who.int/tdr/publications/documents/glp- handbook.pdf>).
- 2 Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
- 3 Drugs from discovery to approval by Rick NG.
- 4 Animal Models in Toxicology, 3rd Edition, Lower and Bryan
- 5 OECD test guidelines.
- 6 Principles of toxicology by Karen E. Stine, Thomas M. Brown.
- 7 Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf>)

PRINCIPLES OF DRUG DISCOVERY (MPL 203T)

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. 12 Hrs
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.
- 2 Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification. 12 Hrs
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.
- 3 Rational Drug Design 12 Hrs
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,
- 4 Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design. Quantitative analysis of Structure Activity Relationship 12 Hrs
History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

- 5 QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA 12 Hrs
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

REFERENCES

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott Markell. In. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
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PHARMACOLOGICAL PRACTICAL - III
(MPL 205PA)

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 to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
6. To determine to 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

PHARMACOLOGICAL PRACTICAL - IV
(MPL 205PB)

1. Drug absorption studies by averted rat ileum preparation.
2. Acute oral toxicity studies as per OECD guidelines.
3. Acute dermal toxicity studies as per OECD guidelines.
4. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
5. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
6. Protocol design for clinical trial.(3 Nos.)
7. Design of ADR monitoring protocol.
8. In-silico docking studies. (2 Nos.)
9. In-silico pharmacophore based screening.
10. In-silico QSAR studies.
11. ADR reporting

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5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
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