

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	10 Hrs
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. 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. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.	
2	10 Hrs
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.	
3	10 Hrs
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.	
4	10 Hrs
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	
c) Ion exchange chromatography	
d) Column chromatography	
e) Gas chromatography	
f) High Performance Liquid chromatography	
g) Ultra High Performance Liquid chromatography	
h) Affinity chromatography	
i) Gel Chromatography	
5	10 Hrs
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

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

- 6 Potentiometry: Principle, working, Ion selective Electrodes and Application of 10 Hrs 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.

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, 5 th 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, 2 nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3 rd 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 Hrs
	<p>a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding.</p> <p>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.</p>	
2	Neurotransmission	12 Hrs
	<p>a. General aspects and steps involved in neurotransmission.</p> <p>b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).</p> <p>c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine).</p> <p>d. Non adrenergic non cholinergic transmission (NANC). Cotransmission</p> <p>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</p> <p>Autonomic Pharmacology Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction</p>	
3	Central nervous system Pharmacology	12 Hrs
	<p>General and local anesthetics</p> <p>Sedatives and hypnotics, drugs used to treat anxiety.</p> <p>Depression, psychosis, mania, epilepsy, neurodegenerative diseases.</p> <p>Narcotic and non-narcotic analgesics.</p>	
4	Cardiovascular Pharmacology	12 Hrs
	<p>Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants, anticoagulants, fibrinolytics and anti- platelet drugs</p>	

- 5 Autocoid Pharmacology 12 Hrs
The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.

REFERENCES

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's
2. 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.
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. Dipro Pharmacology, Pathophysiological approach. 9. Green Pathophysiology for Pharmacists.
10. Robbins & Cortan Pathologic Basis of Disease, 9 th 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. 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 12 Hrs

4 Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Cardiovascular Pharmacology: antihypertensives, 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, 12 Hrs

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

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, 3 rd Edition.
12. David R. Gross. Animal Models in Cardiovascular Research, 2 nd 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	<p>Cell biology</p> <p>Structure and functions of cell and its organelles</p> <p>Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing.</p> <p>Cell cycles and its regulation. Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis.</p> <p>Necrosis and autophagy.</p>	12 Hrs
2	<p>Cell signaling</p> <p>Intercellular and intracellular signaling pathways.</p> <p>Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.</p> <p>Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol.</p> <p>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.</p>	12 Hrs
3	<p>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,</p> <p>Recombinant DNA technology and gene therapy</p> <p>Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology.</p> <p>Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.</p>	12 Hrs
4	<p>Pharmacogenomics</p> <p>Gene mapping and cloning of disease gene.</p> <p>Genetic variation and its role in health/ pharmacology</p> <p>Polymorphisms affecting drug metabolism</p> <p>Genetic variation in drug transporters</p>	12 Hrs

	<p>Genetic variation in G protein coupled receptors</p> <p>Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics</p> <p>Immunotherapeutics</p> <p>Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice</p>	
5	<p>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.</p> <p>b. Biosimilars</p>	12 Hrs
REFERENCES		
<ol style="list-style-type: none"> 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 Cheril D.Helgason and Cindy L.Miller 6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor) 7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor) 8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la. 		

PHARMACOLOGICAL PRACTICAL - I (MPL 105P)

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

Handling of laboratory animals.

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

REFERENCES

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
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)

