SunRise University

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Syllabus

M.Pharm. (Pharmacology)

Master of Pharmacy (M. Pharm.)

SCHEMES FOR INTERNAL ASSESSMENTS AND END SEMESTER EXAMINATIONS (SEM. I & II)
PHARMACOLOGY-MPL

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks	Credit Points
		Continuous Mode	Sessional Exams			Marks	Duration		
			Marks	Duration	Total				
Semester I									
MPL101T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hrs	25	75	3 Hrs	100	4
MPL102T	Advanced Pharmacology-I	10	15	1 Hrs	25	75	3 Hrs	100	4
MPL103T	Pharmacological and Toxicological Screening Methods-I	10	15	1 Hrs	25	75	3 Hrs	100	4
MPL104T	Cellular and Molecular Pharmacology	10	15	1 Hrs	25	75	3 Hrs	100	4
MPL105P	Experimental Pharmacology - I	20	30	6 Hrs	50	100	6 Hrs	150	6
-	Seminar/ Assignment	-	-	-	-	-	-	100	4
							Total	650	26
Semester II									
MPL201T	Advanced Pharmacology II	10	15	1 Hr	25	75	3 Hrs	100	4
MPL202T	Pharmacological and Toxicological Screening Methods-II	10	15	1 Hr	25	75	3 Hrs	100	4
MPL203T	Principles of Drug Discovery	10	15	1 Hr	25	75	3 Hrs	100	4
MPL204T	Clinical Research and Pharmacovigilance	10	15	1 Hr	25	75	3 Hrs	100	4
MPL205P	Experimental Pharmacology - II	20	30	6 Hrs	50	100	6 Hrs	150	6
-	Seminar/Assignment	-	-	-	-	-	-	100	4
							Total	650	26

Schemes for Internal Assessments and End Semester Examinations (Semester III & IV)

Course Code	Course	Internal Assessment				End Semester Exams		Total Marks	Credit Points
		Continuous Mode	Sessional Exams		Total	Marks	Duration		
			Marks	Duration					
Semester III									
MRM301T	Research Methodology and Biostatistics	40	60	2 Hr	100	-	-	100	4
MRM302T	Journal Club	-	-	-	25	-	-	25	1
MRM303P	Discussion /Presentation (Proposal Presentation)	-	-	-	50	-	-	50	2
MRM304P	Research Work	350	-	-	-	-	-	350	14
							Total	525	21
Semester IV									
MRM401T	Journal Club	-	-	-	25	-	-	25	1
MRM402P	Discussion / Presentation (Proposal Presentation)	-	-	-	75	-	-	75	3
MRM403P	Research Work and Colloquium	-	-	-	-	400	1 Hr	400	16
							Total	500	20

PHARMACOLOGY (MPL)

FIRST SEMESTER

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. **UV-Visible spectroscopy:** Introduction, theory, laws, and instrumentation associated with UV-visible spectroscopy, choice of solvents and solvent effect. 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. Applications of IR spectroscopy and data interpretation. **Spectroflourimetry:** Theory of fluorescence, factors affecting fluorescence (characterestics of drugs that can be analyzed by flourimetry), quenchers. Instrumentation and applications of fluorescence spectrophotometer.

   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.
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.
1. **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 chr

omatography. **10 Hrs**

10 Hrs

10 Hrs

10 Hrs

f) High performance liquid chromatography.
g) Ultra high performance liquid chromatography.
h) Affinity chromatography.
i) Gel chromatography.

2. **Electrophoresis:** Principle, instrumentation, working conditions, factors affecting separation and applications of the following: **10 Hrs**
   a) Paper electrophoresis.
   b) Gel electrophoresis.
   c) Capillary electrophoresis.
   d) Zone electrophoresis.
   e) Moving boundary electrophoresis.
   f) Isoelectric focusing.

   X ray Crystallography: Production of X rays, different X ray methods, Bragg's law, rotating crystal technique, X ray powder technique, of crystals and applications of X-ray diffraction.

3. **a. Potentiometry:** Principle, working, Ion selective electrodes and application of potentiometry. **10 Hrs**

   b. 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.

   c. Immunological Assays: RIA (Radio immune assay), ELISA, bioluminescence assays.

REFERENCES

1. Spectrometric Identification of Organic compounds by Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis by Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental Methods of Analysis by Willards, 7th edition, CBS Publishers.
4. Practical Pharmaceutical Chemistry by Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy by William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical Formulation by P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B by 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 by KA. Connors, 3rd Edition, John Wiley & Sons, 1982.

10. Introduction to Spectroscopy by Pavia D.L., Lampman G.M. and Kriz G.S., Harcourt College Publishers, Philadelphia.

11. Analytical Profile of Drug Substance (All volume) by Florey K., Academic Press, Elsevier, Massachusetts.
12. Thin Layer Chromatography: A Laboratory Handbook, Stahl E., Springer, Berlin.
13. Undergraduate Instrumental Analysis, Obonson J.W.R., Marcel Dekker Inc, New York.
14. Absorption Spectroscopy of Organic Molecules by Parikh V.H., Addison-Wesley Publishing Co., London.

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**

   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.

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

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

   Autonomic Pharmacology

   Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction.

3. **Central nervous System Pharmacology:**

   General and local anesthetics

   Sedatives and hypnotics, drugs used to treat anxiety.

   Depression, psychosis, mania, epilepsy, neurodegenerative diseases.

   Narcotic and non-narcotic analgesics.

4. **Cardiovascular Pharmacology:** Diuretics, antihypertensives, antiischemics, anti-

t failure and hyperlipidemia. Hematinics, coagulants , anticoagulants, fibrinolytics and antiplatelet Drugs **12 Hrs**

12 Hrs

12 Hrs

12 Hrs

5. **Autocoid Pharmacology:** The physiological and pathological role of histamine, **12 Hrs**

serotonin, kinins prostaglandins opioid autocoids. Pharmacology of antihistamines, 5HT antagonists.

REFEERENCES

1. Goodman and Gilman, The Pharmacological Basis of Therapeutics by Hardman J.G., Le L., Molinoss P.B., Ruddon R.W. and Gil A.G., Pergamon Press, Oxford.
2. Principles of Pharmacology: The Pathophysiologic Basis of Drug Therapy by Golan D.E., Armstrong E.J., Armstrong A.W., Wolters Kluwer, Alphen aan den Rijn.
3. Basic and Clinical Pharmacology by Katzung, B.G. Prentice Hall International, New Delhi.
4. Pharmacology by Rang M.P., Dale MM, Riter J.M, Churchill Livingstone, London.
5. Biopharmaceutics & Clinical Pharmacokinetics by Gibaldi, M., Pharma Book Syndicate, Hyderabad.
6. Clinical Pharmacy and Therapeutics by Herfindal E.T. and Hirashman J.L., Lippincott Williams and Wilkins, Philadelphia.
7. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists by Kwon Y., Springer, New York.
8. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
9. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
10. Oxford Textbook of Clinical Pharmacology by Graham Smith.
11. Dipiro Pharmacology, Pathophysiological Approach.

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**
   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 practices. 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.
   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 anti-fertility agents.
   Analgesics, anti-inflammatory and antipyretic agents.
   Gastrointestinal drugs: anti ulcer, anti -emetic, anti-diarrheal and laxatives.
4. Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.
   Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics.
   Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents.

Anticancer agents. Hepatop

rotective screening methods. **12 hrs**

12 Hrs

12 Hrs

12 Hrs

5. Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. **12 Hrs**

Iimmunomodulators, 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. Screening Methods in Pharmacology by Turner R.A., Hebborn P., Academic Press, Cambridge.
2. Evaluation of drugs activities by Laurence D.R., Bacharach A.L., Academic Press, Cambridge.
3. Methods in Pharmacology by Arnold S., Springer, New York.
4. Fundamentals of Experimental Pharmacology by Ghosh M.N. Scientific Book Agency, Calcutta.
5. Pharmacological Experiment on Intact Preparations by Mcleod, L.J., Churchill Livingstone, London.
6. Drug discovery and Evaluation by Vogel H.G., Springer-Verlag, Heidelberg.
7. Practicals in Pharmacology by Goyal R.K., B.S. Shah Prakashan, Ahmadabad.
8. Preclinical Evaluation of New Drugs by Gupta S.K., Jaypee Brothers Medical Publishers Private Limited, New Delhi.
9. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA Guidelines.
10. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin.
11. Handbook of Experimental Pharmacology, S.K..Kulkarni.
12. Practical Pharmacology and Clinical Pharmacy, S.K..Kulkarni, 3rd Edition.
13. David R.Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
14. Screening Methods in Pharmacology, Robert A. Turner.
15. Rodents for Pharmacological Experiments, Tapan Kumar Chatterjee.
16. 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. **12 Hrs**
   Cell cycles and its regulation.
   Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis.
   Necrosis and autophagy.
2. **Cell Signaling** **12 Hrs**
   Intercellular and intracellular signaling pathways.
   Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.
   Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol.
   Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.
3. Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, recombinant DNA technology and gene therapy. **12 Hrs**
   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.

4. **Pharmacogenomics** **12 Hrs**

   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.

5. **a. Cell Culture Techniques:** Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures: Isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, calcium influx assays. Principles and applications of flow cytometry. **12 Hrs**

   b. Biosimilars

REFERENCES:

1. The Cell, A Molecular Approach. Geoffrey M Cooper, Sinauer Publisher, USA.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong, Wiley-VCH, Weinheim.
3. Handbook of Cell Signaling by Bradshaw R.A., Denis E.A., Academic Press, Cambridge (Second Edition) Edited by Ralph A. et.al.
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al., Wiley, Colorado.
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller, Springer, New York.
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor), Oxford University Press, Oxford
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor), Oxford University Press, Oxford.
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et al., Wiley, New Jersey.

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 Braford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy.
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
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 - Doglas A Skoog, F. James Holler, Timothy A. Nieman.
7. Vogel‘s Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney.
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L. Mille.
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor).
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor).
11. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author) Jaypee Brothers’ Medical Publishers Pvt. Ltd.

SECOND SEMESTER

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 **60 Hrs**

1. **Endocrine Pharmacology:** Molecular and cellular mechanism of action of hormones such asgrowth 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 ß-lactams, aminoglycosides, quinolones, macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs. **12 Hrs**
3. **Chemotherapy:** **12 Hrs**
   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
4. **GIT Pharmacology:** **12 Hrs**
   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.
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 **12 Hrs**
   Recent Advances in Treatment: Alzheimer's disease, Parkinson's disease, Cancer, Diabetes Mellitus.

REFERENCES

1. Goodman and Gill man's-The Pharmacological Basis of Therapeutics- by Hardman J.G., Limbird Le, Molinoss P.B., Ruddon R.W. and Gil A.G.,
2. Principles of Pharmacology. The Pathophysiologic Basis of Drug Therapy by David E Golan et al., Wolters Kluwer, Alphen aan den Rijn.
3. Basic and Clinical Pharmacology by B.G –Katzung, Prentice Hall International, New Jersey.
4. Pharmacology by H.P. Rang and M.M. Dale, Churchill Livingstone, London.
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, Williams and Wilkins, Philadelphia.
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. Essentials of Medical Pharmacology, K.D.Tripathi.
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) **12 Hrs**
   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.
2. Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. **12 Hrs**
   Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.
   Test item characterization- importance and methods in regulatory toxicology studies.
3. Reproductive toxicology studies, male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) **12 Hrs**
   Genotoxicity studies (Ames test, in vitro and in vivo micronucleus and chromosomal aberrations studies). In vivo carcinogenicity studies.
4. IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. **12 Hrs**
   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.
5. Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics. **12 Hrs**
   Importance and applications of toxicokinetic studies.
   Alternative methods to animal toxicity testing.

REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glphandbook.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. Target discovery and validation-Role of genomics, proteomics and bioinformatics. Role of nucleic acid microarrays, protein microarrays, antisense technologies, siRNAs, antisense oligonucleotides, zinc finger proteins. Role of transgenic animals in target validation. **12 Hrs**
2. **Lead Identification:** combinatorial chemistry & high throughput screening, in silico lead discovery techniques. Assay development for hit identification. **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:** Traditional vs rational drug design, methods followed in traditional drug design, high throughput screening. Concepts of rational drug design. Rational drug design methods: Structure and pharmacophore based approaches. Virtual Screening techniques: Drug likeness screening, concept of pharmacophore mapping and pharmacophore based screening. **12 Hrs**
4. **Molecular Docking:** Rigid docking, flexible docking, manual docking: Docking based screening. De novo drug design. Quantitative analysis of structure activity relationship: History and development of QSAR, SAR versus QSAR, physicochemical parameters, Hansch analysis, Fee-Wilson analysis and relationship between them. **12 Hrs**
5. **QSAR Statistical Methods**: Regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA. Prodrug design: Basic concept, prodrugs to improve patient acceptability, drug solubility, drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design. **12 Hrs**

REFERENCES

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH.
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH.
6. Abby L. Parrill. M. Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development design methodology and analysis. John Wiley & Sons, Inc., New Jersey.

CLINICAL RESEARCH AND PHARMACOVIGILANCE
(MPL 204T)

Scope

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

Objectives

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

- Explain the regulatory requirements for conducting clinical trial.
- Demonstrate the types of clinical trial designs.
- Explain the responsibilities of key players involved in clinical trials.
- Execute safety monitoring, reporting and close-out activities.
- Explain the principles of pharmacovigilance.
- Detect new adverse drug reactions and their assessment.
- Perform the adverse drug reaction reporting systems and communication in pharmacovigilance.

THEORY **60 Hrs**

1. **Regulatory Perspectives of Clinical Trials:** Origin and principles of international conference on harmonization - Good clinical practice (ICH-GCP) guidelines. Ethical Committee: Institutional review board, Ethical guidelines for biomedical research and human participant- Schedule Y, ICMR informed consent process: Structure and content of an informed consent process ethical principles governing informed consent process. **12 Hrs**
2. **Clinical Trials:** Types and design experimental study- RCT and non RCT, observation study: Cohort, case control, cross sectional clinical trial study team roles and responsibilities of clinical trial personnel: Investigator, study coordinator, sponsor, contract research organization and its management **12 Hrs**
3. **Clinical Trial Documentation:** Guidelines to the preparation of documents, preparation of protocol, investigator brochure, case report forms, clinical study report. Clinical trial monitoring: Safety monitoring in CT. Adverse drug reactions: Definition and types, detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, management of adverse drug reactions: Terminologies of ADR. **12 Hrs**
4. **Basic Aspects, Terminologies and Establishment of Pharmacovigilance:** History and progress of pharmacovigilance, significance of safety monitoring, pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centers in hospitals, industry and national programmes related to pharmacovigilance. Roles and responsibilities in pharmacovigilance. **12 Hrs**

5. Methods, ADR reporting and tools used in pharmacovigilance international classification of diseases, international nonproprietary names for drugs, passive and active surveillance, comparative observational studies, targeted clinical investigations and vaccine safety surveillance. Spontaneous reporting system and reporting to regulatory authorities, guidelines for ADRs reporting. Argus, Aris G pharmacovigilance, VigiFlow, statistical methods for evaluating medication safety data. **12 Hrs**

6. Pharmacoepidemiology, pharmacoeconomics, safety pharmacology. **12 Hrs**

REFERENCES

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

PHARMACOLOGICAL PRACTICAL - II
(MPL 205P)

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.
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial (3 Nos.).
17. Design of ADR monitoring protocol.
18. In-silico docking studies (2 Nos.).
19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting.

REFERENCES

1. Fundamentals of experimental Pharmacology -by M.N. Ghosh
2. Hand book of Experimental Pharmacology- S.K. Kulakarni
3. Text book of in-vitro practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.