CENTRAL UNIVERSITY OF PUNJAB, BATHINDA

Master of Pharmacy
(Pharmacology)

Academic Session 2019-21

DEPARTMENT OF PHARMACOLOGY

Course structure for M. Pharm. (Pharmacology)

Course Code	Name of the course	Credit hours	Credit points	Hrs/ wk	Marks
	SEMESTER I				
MPL 101T	Modern Pharmaceutical Analytical techniques	4	4	4	100
MPL102T	Advanced Pharmacology- I	4	4	4	100
MPL103T	Pharmacological and Toxicological Screening Methods- I	4	4	4	100
MPL104T	Cellular and Molecular Pharmacology	4	4	4	100
MPL105P	Pharmacological Practical I (Analytical Instruments Handling, Handling of Laboratory Animals, and Bio-Chemical Analysis)	12	6	12	150
MPL106S	Seminar/Assignment	7	4	7	100
XXX	Inter-Disciplinary Course	2	2	2	50
	Total	**37**	**28**	**37**	**700**
	SEMESTER II				
MPL 201T	Advanced Pharmacology- II	4	4	4	100
MPL202T	Pharmacological and Toxicological Screening Methods- II	4	4	4	100
MPL203T	Principles Of Drug Discovery	4	4	4	100
MPL204T	Clinical Research and Pharmacovigilance	4	4	4	100
MPL205P	Pharmacological Practical II (General Pharmacology, Toxicology, and *In silico* studies)	12	6	12	150
MPC206S	Seminar/Assignment	7	4	7	100
XXX	Inter-Disciplinary Course	2	2	2	50
	Total	**37**	**28**	**37**	**700**
	SEMESTER III				
MRM 301T	Research Methodology & Biostatistics	4	4	4	100
MPL302T	Journal club	1	1	1	25
MPL303T	Discussion/ Presentation (Proposal Presentation)	2	2	-	50
MPL599	Research Work	28	14	-	350
	Total	**35**	**21**	**5**	**525**
	SEMESTER IV				
MPL401T	Journal club	1	1	1	25
MPL402T	Discussion and Final Presentation	3	3	-	75
MPL599	Research Work[#]	31	16	-	400
	Total	**35**	**20**	**-**	**500**

[#]To be evaluated by external expert

Evaluation Criteria for Theory Courses

A. Continuous Assessment: [25 Marks]
   i. Surprise Test (minimum three) - Based on Objective Type Tests (10 Marks)
   ii. Term paper (10 Marks)
   iii. Assignment(s) (5 Marks)
B. Mid Semester Test-1: Based on Subjective Type Test [25 Marks]
C. Mid Semester Test-2: Based on Subjective Type Test [25Marks]
D. End-Term Exam: Based on Objective Type Tests [25 Marks]

Evaluation Criteria for Practical Courses

Item	Synopsis	Experiment	Practical Note book and day to day evaluation	Viva voce
Marks	20	50	50	30

PHARMACOLOGY (MPL)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPL 101T)

Scope

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

Objectives

After completion of course student is able to know about,

- Chemical 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. Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics 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 ^{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: **10 Hrs**
   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. 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) Iso-electric focusing
   (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.
6. 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. Pharmaceutical Quality by design, qualitative and quantitative analysis of drugs and pharmaceuticals including impurity profiling in Active Pharmaceutical Ingredients (APIs) as per regulatory requirements, ICH guidelines for analysis of drugs and pharmaceuticals.

REFERENCES

1. Spectrometric Identification of Organic compounds – Robert M Silverstein, 8th edition, John Wiley & Sons, 2015.
2. Principles of Instrumental Analysis – Doglas A Skoog, F. James Holler, Timothy A. Nieman, 6th edition, Cengage, 2014.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publisher, 2004.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 2007.
5. Organic Spectroscopy – William Kemp, 3rd edition, ELBS, 2008.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd edition, CBS Publishers, New Delhi, 2007.
7. Pharmaceutical Analysis – Modern Methods – Part B – J W Munson, Vol 11, Marcel, Dekker Series 1984 (Reprint 2012)
8. Spectroscopy of Organic Compounds, 6th edn., P. S. Kalsi, Wiley Eastern Ltd., Delhi, 2016.
9. Textbook of Pharmaceutical Analysis, KA. Connors, 3rd Edition, John Wiley & Sons, 2007.
10. Introduction to spectroscopy. 4th Edition, Pavia DL, Lampman GM, Kriz GS, Vyvyan JA.; Cengage Learning, 2008

11. Pharmaceutical quality by design: a practical approach. Schlindwein WS, Gibson M, editors. John Wiley & Sons; 2018.
12. HPLC in the Pharmaceutical Industry, (Volume 47) (Drugs and the Pharmaceutical Sciences Series) – Edited by Godwin W. Fong, Stanley K. Lam, CRC press, 2010
13. Handbook of Pharmaceutical Analysis (Volume 117) (Drugs and the Pharmaceutical Sciences Series) Edited by Lena Ohannesian, Anthony J. Streeter, Marcel Dekker Inc. 2008

ADVANCED PHARMACOLOGY – 1
(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. **12 Hrs**
   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. **12 Hrs**
   b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters – Adrenaline and Acetylcholine).
   c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters – histamine, serotonin, dopamine, GABA, glutamate and glycine).
   d. Non adrenergic non cholinergic transmission (NAN). Co-transmission

   Systemic Pharmacology

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

   Autonomic Pharmacology

   Parasympatho-mimetics and -lytics, sympatho-mimetics 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. Autacoid Pharmacology: The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autacoids. Pharmacology of antihistamines, SHT antagonists. **12 Hrs**

REFERENCES

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's 13th edition by Laurence Brunton, Bjorn Knollman and Randa Hilal-Dandan, McGraw-Hill Education, 2017.
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy,4th edition by David E Golan, Armen H, Tashjian Jr, Ehrin J, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers, 2016.
3. Basic and Clinical Pharmacology by B. G Katzung, 14th edition, McGraw-Hill, 2018.
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott, New York: ADIS Health Science Press, 1983.
5. Applied bioharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu. 7th edition, McGraw-Hill Education, 2015
6. Graham Smith. Oxford textbook of Clinical Pharmacology, 3rd edition, Oxford University Press, 2002.
7. Avery Drug Treatment by Trevor M. Speight and Nicholas H.G. Holford, 4th edition, Wiley India Pvt Ltd, 2012.
8. Dipiro Pharmacology: A pathophysiological approach. 10th edition, McGraw-Hill Education, 2017.
9. Green Pathophysiology for Pharmacists.
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology), Elsevier, 2014.
11. A Complete Textbook of Medical Pharmacology 2nd edition by Dr. S. K. Srivastava published by APC Avichal Publishing Company, 2017.
12. K.D. Tripathi, Essentials of Medical Pharmacology, 8th edition, Jaypee Brothers Medical Pub, 2018.
13. Modern Pharmacology with Clinical Applications, 6th edition, Craig Charles R. & Stitzel Robet E., Lippincott Publishers, 2003.
14. Clinical Pharmacokinetics & Pharmacodynamics: Concepts and Applications, 4th edition, Malcolm Rowland and Thomas N. Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers, 2010.
15. Applied Biopharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists, 7th edition, 2016.
16. Modern Pharmacology, Craig CR. & Stitzel RE, 6th edition. Little Brown & Company 2012.
17. Gene Therapy: Treating Disease by Repairing Genes (The New biology Series)– Joseph Panno, Viva books private limited, 2017
18. Handbook of Drug Metabolism (Volume 186) (Drugs and the Pharmaceutical Sciences Series) Edited by Paul G Pearson, Larry C. Wienkers, 2nd Edition, Informa Healthcare, 2009
19. Oxford Handbook of Clinical Pharmacy – Philip Wiffen, Marc Mitchell, Melanie Snelling, Nicola Stoner, indian Edition, Oxford university press, 2008
20. New Drug Approval Process: Accelerating Global Registrations – Richard A. Guarino (Ed.), 4th Edition, Marcel Dekker Inc, 2008
21. Drug-drug interactions, (Volume 179) (Drugs and the Pharmaceutical Sciences Series) Edited by A. David Rodrigues, 2nd Edition, Informa Healthcare, 2008

22. The chemical basis of Drug Action (Volume 2) (Foundations of Molecular Pharmacology Series) – J.B. Stenlake, The Anthlone Press, 2009
23. Drug Facts Comparisons 2015 – Facts & comparisons, 2014
24. Animal and Translational Models for CNS Drug Discovery (3 volumes Set)- Edited by Robert A. Mcarthur, Franco Borsini, Academic press, 2008

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-1
(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. **12 Hrs**
   Transgenic animals: Production, maintenance and applications Anesthesia 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 co-ordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti-epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimer's 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: ani-asthmatics, drugs for COPD and anti-allergic.
   Reproductive Pharmacology: Aphrodisiacs and antifertility 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. **12 Hrs**
   Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti-cancer agents. Hepatoprotective screening methods.

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

Immunomodulators, lmmunosuppressants and immunostimulants

General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogeneous 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, 2011.
2. Screening methods in Pharmacology by Robert Tuner. A., 2013.
3. Evaluation of drugs activities, 1st edition by Laurence and Bachrach, 2005.
4. Methods in Pharmacology by Arnold Schwartz 2013 (reprint of 1st edition of 1971)
5. Fundamentals of experimental Pharmacology by M.N. Ghosh, 2011.
6. Pharmacological experiment on intact preparations by Churchill Livingstone, 1970.
7. Drug discovery and Evaluation by Vogel H.G. 2011.
8. Experimental Pharmacology by R. K. Goyal
9. Preclinical evaluation of new drugs 2nd edition by S. K. Gupta,2009.
10. Handbook of Experimental pharmacology, S.K. Kulkarni, 2016.
11. Practical Pharmacology and Clinical Pharmacy, S.K. Kulkarni, 3rd Edition. 2008.
12. David R. Gross. Animal Models in Cardiovascular Research, 3rd revised Edition, Kluwer Academic Publishers, London, UK. 2009.
13. Screening Methods in Pharmacology, Robert A. Turner. 2013.
14. Rodents for Pharmacological Experiments, Dr. Tapan Kumar Chatterjee. 2018 (reprint)
15. Practical Manual of Experimental and Clinical Pharmacology 2nd edition by Bikash Medhi (Author), Ajay Prakash (Author), 2017.

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 **12 Hrs**
   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.
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, (IP_3), 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 **12 Hrs**
   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.
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, function omics, nutrigenomics.
Immunotherapeutic
Types of immunotherapeutic, humanization antibody therapy, Immunotherapeutic in clinical practice

5. a. Cell culture techniques **12 Hrs**

Basic equipment 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

REFERENCES:

1. The Cell, A Molecular Approach. 6th edition, Geoffrey M Cooper. 2013.
2. Pharmacogenomics: The Search for individualized Therapies. Edited by J. Licinio and M - L. Wong, 2009.
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, 2012.
5. Basic Cell Culture protocols, 4th edition by Cheril D. Helgason and Cindy L.Miller, 2013.
6. Basic Cell Culture (Practical Approach) 2nd revised edition by M. Davis (Editor), 2001.
7. Animal Cell Culture: A Practical Approach 3rd revised edition by John R. Masters (Editor) 2000.
8. Current protocols in molecular biology vol l to VI edited by Frederick M. Ausuvel et la. 1988.

PHARMACOLOGICAL PRACTICAL-I
(MPL 105P)

A. ANALYTICAL INTRUMENTS HANDLING)

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. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
8. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

B. HADNLING 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.

C. BIO-CHEMICAL ANALYSIS

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 Braford/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 software
13. Enzyme inhibition and induction activity

REFERENCES:

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines
2. Fundamentals of experimental Pharmacology by M.N. Ghosh, 2011.
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.2016.
4. Drug discovery and Evaluation by Vogel H.G.2011.
5. Spectrometric Identification of Organic compounds 8th edition - Robert M Silverstein. 2015.
6. Principles of Instrumental Analysis 6th edition- Doglas A Skoog, F. James Holler, Timothy A. Nieman.2014.
7. Vogel's Text book of quantitative chemical analysis 5th edition - Jeffery, Basset, Mendham, Denney. 1989.
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille, Springer, 2013.
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor) 2001.
10. Animal Cell Culture: A Practical Approach 3rd revised edition by John R. Masters (Editor) 2000.
11. Practical Manual of Experimental and Clinical Pharmacology 2nd edition by Bikash Medhi(Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd, 2017.
12. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics – Carl A Burtis, Edward R. Ashwood, David E. Burns, 5th Edition, Elsevier, 2014

Course Title: Seminar/Assignment

Paper Code: MPL106S

L	T	P	Cr
-	-	-	4

Learning outcome: Students who successfully complete this course will be able to

- Perform literature review on a given topic
- Prepare a report on a given topic
- Prepare a power point presentation on a given topic

Evaluation criteria:

- Literature survey/background information
- Organization of content
- Physical presentation
- Questions and answers
- Report evaluation

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 **12 Hrs**
   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
2. Chemotherapy **12 Hrs**
   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.
3. Chemotherapy
   Drugs used in Protozoal Infections **12 Hrs**
   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 Hrs 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 **12 Hrs**
   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

REFERENCES

1. The Pharmacological basis of therapeutics 13th edition - Goodman and Gilman's, 2017.
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy 4th edition by David E Golan et al. 2016.
3. Basic and Clinical Pharmacology 14th edition by B.G –Katzung, 2018.
4. Pharmacology 8th edition by H.P. Rang and M.M. Dale. Elsevier, 2015.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.1983.
6. Text book of Therapeutics, drug and disease management 7th edition by E T. Herfindal and Gourley. 2000.
7. Applied biopharmaceutics and Pharmacokinetics 7th edition by Leon Shargel and Andrew B.C.Yu.2015.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists. 7th edition, 2016.
9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology) 2014.
10. A Complete Textbook of Medical Pharmacology 2nd edition by Dr. S.K Srivastava published by APC Avichal Publishing Company. 2017.
11. K.D.Tripathi. Essentials of Medical Pharmacology, 8th edition, 2018.
12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy 4th edition, by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers, 2018.

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 **60Hrs**

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
3. Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenicity 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. Engineered nanomaterials, drug delivery, nanotoxicology and regulatory requirements, Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. **12 Hrs**
   Alternative methods to animal toxicity testing.

REFERENCES;

1. Hand book on GLP, Quality practices for regulated non-clinical research and development 2nd edition, (http://www.who.int/tdr/publications/documents/glp-handbook.pdf).WHO, 2008.
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 3rd edition by Rick NG. Wiley Blackwell, 2015.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan
5. OECD test guidelines.
6. Principles of toxicology 3rd edition by Karen E. Stine, Thomas M. Brown. 2015.
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)
8. Nanoparticle Technology for Drug Delivery (Volume 159) (Drugs and the Pharmaceutical Sciences Series) – Edited by Ram B. Gupta, Uday B. Komepella, 2nd Edition, Taylor & Frabcis Group, 2006

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 of 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- combination chemistry & High throughput screening, in silico lead discovery techniques, Assay development of hit identification. **12 Hrs**

   Protein structure

   Level 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. **12 Hrs**

   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 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**

REFRENCES

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.2nd edition Springer New York Dordrecht Heidelberg London. 2018
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH. 1993.
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH. 1998.
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, 2007.

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 **12 Hrs**
   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.

2. Clinical Trials: Types and Design **12 Hrs**
   Experimental Study- RCT and Non RCT,
   Observation Study: Cohort, Case Control, Cross sectional
   Clinical Trial Study Team
   Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management

3. Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT **12 Hrs**
   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.

4. Basic aspects, terminologies and establishment of pharmacovigilance **12 Hrs**
   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 centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance
5. Methods, ADR reporting and tools used in Pharmacovigilance **12 Hrs**
   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.
6. Pharmacoepidemiology, Pharmacoeconomics, safety pharmacology (ICH Guideline) **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, 2nd edition, John Wiley and Sons.2010.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, March 2013, Wiley Publications.
6. Handbook of clinical Research. 2nd edition Julia Lloyd and Ann Raven Ed. Churchill Livingstone. 1994.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes. 2001.

PHARMACOLOGICAL PRACTICAL II
(MPL 205P)

A. GENERAL PHARMACOLOGY

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.

B. TOXICOLOGY

1. Acute oral toxicity studies as per OECD guidelines.
2. Acute dermal toxicity studies as per OECD guidelines.
3. Repeated dose toxicity studies- Serum biochemical, hematological, urine analysis, functional observation tests and histological studies.
4. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
5. Protocol design for clinical trial. (3 Nos.)
6. Design of ADR monitoring protocol and reporting.

C. *IN SILICO* STUDIES

1. In silico physico chemical prediction
2. ADME prediction tools and software
3. In-silico docking studies. (2 Nos.)
4. In-silico pharmacophore-based screening.
5. In-silico QSAR studies.

REFERENCES

1. Fundamentals of experimental Pharmacology-by M. N .Ghosh 2011.
2. Hand book of Experimental Pharmacology-S.K.Kulakarni.2016.
3. Text book of in-vitro practical Pharmacology by Ian Kitchen. 1984.
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal Choudhary and William Thomsen. 2017
5. Applied biopharmaceutics and Pharmacokinetics 7th edition by Leon Shargel and Andrew B.C.Yu.2015.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists. 7th edition, 2016.
7. Computational Toxicology: Risk Assessment for chemicals (Wiley Series on technologies for the pharmaceutical industry) Edited by Sean Ekins, John Wiley & Sons, 2018

Course Title: Seminar/Assignment

Paper Code: MPL206S

L	T	P	Cr
-	-	-	4

Learning outcome: Students who successfully complete this course will be able to

- Perform literature review on a given topic
- Prepare a report on a given topic
- Prepare a power point presentation on a given topic

Evaluation criteria:

- Literature survey/background information
- Organization of content
- Physical presentation
- Questions and answers
- Report evaluation

Semester III

MRM 301T - Research Methodology & Biostatistics

UNIT – I

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

UNIT – II

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

UNIT – III

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

UNIT – IV

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

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

REFERNCES:

1. Gupta, S. (2005). *Research methodology and statistical techniques*, Deep & Deep Publications (p) Ltd. New Delhi.
2. Kothari, C. R. (2008.) *Research methodology(s)*, New Age International (p) Limited. New Delhi
3. Best J. W., Khan J. V. (Latest Edition) *Research in Education*, Prentice Hall of India Pvt. Ltd.
4. *Safe science: promoting a culture of safety in academic chemical research*; National Academic Press, www.nap.edu.
5. Copyright Protection in India [website: http: copyright.gov.in].
6. World Trade Organization [website: www.wto.org].
7. Wadedhra, B.L. Law Relating to Patents, Trademarks, Copyright Design and Geographical Indications. Universal Law Publishing, New Delhi. Latest Edition.
8. Gookin, D. 2007. MS Word for Dummies. Wiley.
9. Harvey, G. 2007. MS Excel for Dummies. Wiley
10. Sinha, P.K. Computer Fundamentals. BPB Publications.
11. Norman, G. and Streiner, D. (3rd edn) (2008). *Biostatistics: The Bare Essentials*. Decker Inc., Canada.
12. Sokal, R.R. and Rohlf, F.J. (1994). *Biometry: The Principles and Practices of Statistics in Biological Research*, W.H. Freeman and Company, New York.
13. Bolton, S., & Bon, C. (2009). *Pharmaceutical statistics: practical and clinical applications*. CRC Press
14. Jagadeesh G., Murthy S., Gupta YK, Prakash A. (2010) Biomedical Research from Ideation to Publication. Walters Kluwer and Lippincott Williams and Wilkins.

Course Title: Journal Club

Paper Code: MPL302T

L	T	P	Cr
-	-	-	1

Course Title: Discussion/ Presentation (Proposal Presentation)

Paper Code: MPL303T

L	T	P	Cr
-	-	-	2

Course Title: Research Work

Paper Code: MPL599

L	T	P	Cr
-	-	-	14

Learning outcome: Students who successfully complete this course will be able to

- Design a research problem and prepare synopsis
- Plan and execute experiments in the laboratory
- Interpret and analyze the results

Evaluation criteria:

- Literature survey/background information
- Organization of content
- Physical presentation
- Questions and answers
- Report evaluation

Semester IV

Course Title: Journal Club

Paper Code: MPL401T

L	T	P	Cr
-	-	-	1

Course Title: Discussion/ Presentation
Paper Code: MPL402T

L	T	P	Cr
-	-	-	3

Course Title: Research Work: MPL599

L	T	P	Cr
-	-	-	16

Learning outcome: Students who successfully complete this course will be able to

- Design a research problem and prepare synopsis
- Plan and execute experiments in the laboratory
- Interpret and analyze the results

Evaluation criteria:

- Literature survey/background information
- Organization of content
- Physical presentation
- Questions and answers
- Thesis evaluation
- Viva-voce

The following are some of the **modes of classroom transaction**

1) Lecture
2) Demonstration
3) Lecture cum demonstration
4) Project Method
5) Seminar
6) Group discussion
7) Focused group discussion
8) Team teaching
9) Experimentation
10) Tutorial
11) Problem solving
12) Self-learning

The following **tools** can be used in **different transactional modes**:

- PPT
- Facebook WhatsApp Video
- Multimedia packages TED Talks
- google drive

Software tools

- Tracker
- ChemDraw
- Schrodinger
- Maestro /Autodock, etc.
- Blast
- Endnote/reference manager, etc.