Scheme and Syllabus

M. Pharmacy
Pharmacology

Batch 2017 onwards

PTU

ਆਈ. ਕੇ. ਗੁਜਰਾਲ ਪੰਜਾਬ ਟੈਕਨੀਕਲ ਯੂਨੀਵਰਸਿਟੀ

By
Board of Studies Pharmacy
Department of Academics

First Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	External	Total	
MPL101T	Modern Pharmaceutical Analytical Techniques	4	-	25	75	100	4
MPL102T	Advanced Pharmacology-I	4	-	25	75	100	4
MPL103T	Pharmacological & Toxicological Screening Methods-I	4	-	25	75	100	4
MPL104T	Cellular & Molecular Pharmacology	4		25	75	100	4
MPL105P	Experimental Pharmacology-I	-	12	50	100	150	6
-	Seminar/Assignment#	-	7	-	-	100	4
	Total	**16**	**19**	**150**	**400**	**650**	**26**

- # Minimum five seminar/assignment each of 20 marks per semester

Second Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	External	Total	
MPL201T	Advanced Pharmacology II	4	-	25	75	100	4
MPL202T	Pharmacological & Toxicological Screening Methods-II	4	-	25	75	100	4
MPL203T	Principles of Drug Discovery	4	-	25	75	100	4
MPL204T	Clinical Research & Pharmacovigilance	4		25	75	100	4
MPL205P	Experimental Pharmacology-II	-	12	50	100	150	6
-	Seminar/Assignment#	-	7	-	-	100	4
	Total	**16**	**19**	**150**	**400**	**650**	**26**

- # Minimum five seminar/assignment each of 20 marks per semester

Third Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	**External**	**Total**	
MRM301T	Research Methodology & Biostatistics*	4	-	25	75	100	4
-	Journal Club	1	-	25	-	25	1
-	Discussion / Presentation (Proposal Presentation)	2	-	50	-	50	2
-	Research Work*	-	28	-	350	350	14
	Total	**7**	**28**	**100**	**425**	**525**	**21**

- *Non -University Exam

Fourth Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	External	Total	
-	Journal Club	1	-	25	-	25	1
-	Research Work	-	31	-	400	400	16
-	Discussion/Final Presentation	3	-	75	-	75	3
-	Co-curricular Activities	-	-	Satisfactory/Unsatisfactory			2*
Total		**4**	**31**	**100**	**400**	**500**	**22**

**Note: Required credit points 02 for satisfactory; Less than 02 credit points unsatisfactory*

***Credits not included towards calculation of CGPA**

Semester Wise Credits Distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations & Other Scholarly Activities)	02*
Total Credit Points	**93 + 2* = 95**

- *Credit Points for Co-curricular Activities
- *Credits not included towards calculation of CGPA
- *The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University

Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points
Participation in National Level Seminar/ Conference/ Workshop/ Symposium/ Training Programs (related to the specialization of the student) OR Academic Award/Research Award from State Level/National Agencies	02
Participation in International Level Seminar/ Conference/ Workshop/ Symposium / Training Programs (related to the specialization of the student) #	02
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science)*	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science)*$	02

- #International Conference held even in India will be considered for award of Credit Points.
- *Only those research / review publications will be considered which have been published during the tenure of M. Pharm. Course.
- $ International Journal: The Editorial Board outside India.

Academic Work

The department / teaching staff of respective courses shall maintain a regular record of attendance in Theory, Practical, Seminar, Assignment, Journal Club, and Discussion with the supervisor, Research work presentation and Dissertation.

Program Committee

1. M. Pharm. Programme shall have a Programme Committee constituted by the Head of the Institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows:
   a. A teacher at the cadre of Professor shall be the Chairperson
   b. One Teacher from each M. Pharm. Specialization
   c. Four student representatives (two from each academic year), nominated by the Head of the Institution
3. Duties of the Programme Committee:
   a. Periodically review the progress of the classes.
   b. Discuss the problems concerning curriculum, syllabus and the conduct of classes.
   c. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.

Sessional Exams

- Two sessional exams shall be conducted for each theory/practical course
- The average marks of two sessional exams shall be computed for internal assessment
- Sessional exam shall be **conducted for 30 marks** for theory and shall be **computed for 15 marks**.
- Sessional exam for practical shall be **conducted for 40 marks** and shall be **computed for 30 marks**.

Question Paper Pattern for Theory Sessional Examinations

Multiple Choice Questions (MCQs) **OR** Objective Type Questions (5 x 2) (Answer all the questions)	10 x 1 = 10 **OR** 05 x 2 = 10
Short Answers (Answer 2 out of 3)	2 x 5 = 10
Long Answers (Answer 1 out of 2)	1 x 10 = 10
Total	**30 Marks**

Question Paper Pattern for Practical Sessional Examinations

Synopsis	10
Experiments	25
Viva voce	05
Total	**40 Marks**

Internal Assessment

- The internal assessment will have two components i.e. **Continuous Mode** and **Sessional Exams**

1. Theory Courses having Internal of 25 Marks the scheme of internal award is:
   - Sessional Exams: 15 Marks
   - Continuous Mode: 10 Marks

Continuous Mode Scheme

Criteria	Maximum Marks
*Attendance (as per table given below)	08
Student – Teacher interaction	02
Total	**10**

2. Practical Courses having Internal of 50 Marks the scheme of internal award is:
   - Sessional Exams: 30 Marks
   - Continuous Mode: 20 Marks

Continuous Mode Scheme

Criteria	Maximum Marks
*Attendance (as per table given below)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	**20**

***Guidelines for the Allotment of Marks for Attendance**

Percentage of Attendance	Theory (Maximum Marks 08)	Practical (Maximum Marks 10)
95 – 100	08	10
90 – 94	06	7.5
85 – 89	04	5
80 – 84	02	2.5
Less than 80	0	0

1st SEMESTER

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPL101T	Modern Pharmaceutical Analytical Techniques	4	-	25	75	1	3	4

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

1. Chemicals and Excipients.
2. The analysis of various drugs in single and combination dosage forms.
3. Theoretical and practical skills of the instruments.

Module 01 **10 Hour**

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, Data Interpretation

Spectroflourimetry

- Theory of Fluorescence
- Factors affecting fluorescence (characteristics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation
- Applications of fluorescence spectrophotometer

Flame Emission Spectroscopy and Atomic Absorption Spectroscopy

- Principle, Instrumentation, Interferences and Applications

Module 02 **10 Hours**

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

Module 03 **10 Hours**

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
- Applications of Mass spectroscopy

Module 04 **10Hours**

Chromatography

Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

- Thin Layer chromatography
- High Performance Thin Layer Chromatography
- Ion exchange chromatography
- Column chromatography
- Gas chromatography
- High Performance Liquid chromatography
- Ultra High Performance Liquid chromatography
- Affinity chromatography
- Gel Chromatography

Module 05 **10Hours**

Electrophoresis

Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

- Paper electrophoresis
- Gel electrophoresis
- Capillary electrophoresis
- Zone electrophoresis
- Moving boundary electrophoresis
- Isoelectric focusing

X ray Crystallography

- Production of X rays
- Different X ray diffraction methods
- Bragg‘s law, Rotating crystal technique, X ray powder technique
- Types of crystals and applications of X-ray diffraction

Module 06 **10 Hours**

Potentiometry

- Principle, working, ion selective electrodes
- Application of potentiometry

Thermal Techniques

- Principle, thermal transitions and instrumentation (Heat flux and power-compensation and designs)
- Modulated DSC, Hyper DSC
- Experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence
- Advantage and disadvantages
- Pharmaceutical applications

Differential Thermal Analysis (DTA)

- Principle, instrumentation
- Advantage and disadvantages
- Pharmaceutical applications
- Derivative differential thermal analysis (DDTA)

TGA

- Principle, instrumentation
- Factors affecting results
- Advantage and disadvantages
- Pharmaceutical applications

Recommended Books (Latest editions)

1. Spectrometric Identification of Organic Compounds - Robert M Silverstein, John Wiley & Sons.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, Eastern press, Bangalore.
3. Instrumental methods of analysis – Willards, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, CBS Publishers, New Delhi.
5. Organic Spectroscopy - William Kemp, ELBS.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi,CBS Publishers, New Delhi.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.
8. Spectroscopy of Organic Compounds, P.S. Kalsi, Wiley Estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, K. A. Connors, John Wiley & Sons.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPL102T	Advanced Pharmacology - I	4	-	25	75	1	3	4

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

1. Discuss the pathophysiology and pharmacotherapy of certain diseases.
2. Explain the mechanism of drug actions at cellular and molecular level.
3. Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases.

Module 01 **12Hours**

General Pharmacology

Pharmacokinetics

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

Pharmacodynamics

- Mechanism of drug action
- The relationship between drug concentration and effect Receptors
- Structural and functional families of receptors
- Quantitation of drug receptors interaction and elicited effects

Module 02 **12Hours**

Neurotransmission

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

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

Autonomic Pharmacology

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

Module 03 **12Hours**

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)*

Central Nervous System Pharmacology

- General and local anesthetics
- Sedatives and hypnotics
- Drugs used to treat anxiety
- Depression, psychosis, mania, epilepsy, neurodegenerative diseases

Module 04 **12 Hours**

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)*

Cardiovascular Pharmacology

- Diuretics
- Antihypertensives
- Antiischemics
- Anti- Arrhythmics,
- Drugs for Heart Failure and Hyperlipidemia
- Hematinics
- Coagulants
- Anticoagulants
- Fibrinolytics
- Anti-Platelet Drugs

Module 05 **12 Hours**

Autocoid Pharmacology

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

Recommended Books (Latest editions)

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman‘s Principles of Pharmacology.
2. 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. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.
10. Robbins & Cortan Pathologic Basis of Disease (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.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPL103T	Pharmacological & Toxicological Screening Methods - I	4	-	25	75	1	3	4

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, student shall be able to

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

Module 01 **12 Hours**

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
- Good laboratory practice
- Bioassay-Principle, scope and limitations and methods

Module 02 **12 Hours**

- 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

Module 03 **12 Hours**

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

Module 04 **12 Hours**

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

- CardiovascularPharmacology:anti-hypertensives,anti-arrythmics,anti-anginal,anti-atherosclerotic agents and diuretics
- Drugs for metabolic disorders like anti-diabetic, anti-dyslipidemic agents
- Anti-cancer agents
- Hepatoprotective screening methods

Module 05 **12 Hours**

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

- Immunomodulators, Immunosuppressants and immunostimulants

General Principles of Immunoassay

- Theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems
- Immunoassay methods evaluation; protocol outline, objectives and preparation
- Immunoassay for digoxin and insulin

Limitations of animal experimentation and alternate animal experiments
Extrapolation of in vitro data to preclinical and preclinical to humans

Recommended Books (Latest editions)

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, S. K. Kulkarni.
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni.
12. David R.Gross. Animal Models in Cardiovascular Research, 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)

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPL104T	Cellular & Molecular Pharmacology	4	-	25	75	1	3	4

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 this course, the student should be able to

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

Module 01 **12 Hours**

Cell Biology

- Structure and functions of cell and its organelles
- Genome organization
- Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing
- Cell cycles and its regulation
- Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis
- Necrosis and autophagy

Module 02 **12 Hours**

Cell Signalling

- Intercellular and intracellular signalling 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 signalling pathways: cyclic AMP signalling pathway, mitogen-activated protein kinase (MAPK) signalling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signalling pathway

Module 03 **12 Hours**

Pilot Plant Scale Up

- Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting

Recombinant DNA Technology and Gene Therapy

- Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors
- Applications of recombinant DNA technology
- Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy

Module 04 **12 Hours**

Pharmacogenomics

- Gene mapping and cloning of disease gene
- Genetic variation and its role in health/ pharmacology
- Polymorphisms affecting drug metabolism
- Genetic variation in drug transporters
- Genetic variation in G protein coupled receptors
- Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics

Immunotherapeutics

- Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

Module 05 **12 Hours**

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

Biosimilars

Recommended Books (Latest editions)

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, 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.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPL105P	Experimental Pharmacology - I	-	12	50	100	6	6	6

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

Recommended Books (Latest editions)

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

2nd SEMESTER

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPL201T	Advanced Pharmacology - II	4	-	25	75	1	3	4

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

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

Module 01 **12 Hours**

Endocrine Pharmacology

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

Module 02 **12 Hours**

Chemotherapy

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

Module 03 **12 Hours**

Chemotherapy

- Drugs used in Protozoal Infections
- Drugs used in the treatment of Helminthiasis
- Chemotherapy of cancer

Immunopharmacology

- Cellular and biochemical mediators of inflammation and immune response
- Allergic or hypersensitivity reactions
- Pharmacotherapy of asthma and COPD
- Immunosuppressants and Immunostimulants

Module 04 **12 Hours**

GIT Pharmacology

- Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome

Chronopharmacology

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

Module 05 **12 Hours**

Free Radicals Pharmacology

- Generation of free radicals
- role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer
- Protective activity of certain important antioxidant

Recent Advances in Treatment

- Alzheimer's Disease
- Parkinson's Disease
- Cancer
- Diabetes Mellitus

Recommended Books (Latest editions)

1. The Pharmacological basis of therapeutics- Goodman and Gillman's.
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G –Katzung.
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Textbook of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.
9. Robbins & Cortan Pathologic Basis of Disease, (Robbins Pathology).
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company.
11. KD.Tripathi. Essentials of Medical Pharmacology.
12. 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

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPL202T	Pharmacological & Toxicological Screening Methods-II	4	-	25	75	1	3	4

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

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

Module 01 **12 Hours**

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

Module 02 **12 Hours**

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

Module 03 **12 Hours**

- Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III)
- Teratogenecity studies (segment II)
- Genotoxicity studies (Ames Test, *in vitro* and *in vivo* Micronucleus and Chromosomal aberrations studies)

Module 04 **12 Hours**

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

Module 05 **12 Hours**

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

Recommended Books (Latest editions)

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (http://www.who.int/tdr/publications/documents/glp- handbook.pdf).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 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, 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).

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPL203T	Principles of Drug Discovery	4	-	25	75	1	3	4

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 this course, the student should be able to

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

Module 01 **12 Hours**

Introduction

- 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

Module 02 **12 Hours**

- Lead Identification- combinatorial chemistry & high throughput screening, *in silico* lead discovery techniques
- Assay development for hit identification
- Protein structure, Levels of protein structure, Domains, motifs, and folds in protein structure
- Computational prediction of protein structure: Threading and homology modeling methods
- Application of NMR and X-ray crystallography in protein structure prediction

Module 03 **12 Hours**

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

Module 04 **12 Hours**

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

Module 05 **12 Hours**

- 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, Pro-drugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action Rationale of pro-drug design and practical consideration of pro-drug design

Recommended Books (Latest editions)

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. Humana Press Inc.
2. Darryl León. Scott Markel, *In Silico* Technologies in Drug Target Identification and Validation, 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.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPL204T	Clinical Research & Pharmacovigilance	4	-	25	75	1	3	4

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

1. Explain the regulatory requirements for conducting clinical trial.
2. Demonstrate the types of clinical trial designs.
3. Explain the responsibilities of key players involved in clinical trials.
4. Execute safety monitoring, reporting and closeout activities.
5. Explain the principles of Pharmacovigilance.
6. Detect new adverse drug reactions and their assessment.
7. Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance.

Module 01 **12 Hours**

Regulatory Perspectives of Clinical Trials

- Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines

Plant Layout

- Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout

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

Module 02 **12 Hours**

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

Module 03 **12 Hours**

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

Module 04 **12 Hours**

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 centres in Hospitals
- Industry and National programmes related to pharmacovigilance
- Roles and responsibilities in Pharmacovigilance

Module 05 **12 Hours**

Methods, ADR Reporting and Tools Used In Pharmacovigilance

- International classification of diseases
- International Non- proprietary names for drugs
- Passive and Active surveillance
- Comparative observational studies
- Targeted clinical investigations and Vaccine safety surveillance
- Spontaneous reporting system
- Reporting to regulatory authorities
- Guidelines for ADRs reporting

- Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data

Pharmacoepidemiology
Pharmacoeconomics
Safety pharmacology

Recommended Books (Latest editions)

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health.
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.
3. Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs, 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.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPL205P	Experimental Pharmacology - II	-	12	50	100	6	6	6

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

Recommended Books (Latest editions)

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh.
2. Hand book of Experimental Pharmacology-S.K.Kulakarni.
3. Textbook 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.

3rd SEMESTER

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MRM301T	Research Methodology & Biostatistics	4	-	25	75	1	3	4

Module 01 **12 Hours**

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

Module 02 **12 Hours**

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

Module 03 **12 Hours**

Medical Research

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

Module 04 **12 Hours**

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

Module 05 **12 Hours**

Declaration of Helsinki

- History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care

Recommended Books (Latest editions)

1. Basic & Clinical Biostatistics, Beth Dawson and Robert G. Trapp. Lange Medical Books/McGraw-Hill Medical Publishing Division.
2. Research Methdology, R. Panneerselvam, PHI Learning Pvt. Limited, Delhi.
3. Methods in Biostatistics, B.K. Mahajan. JAYPEE Brothers Medical Publishers (P) Ltd.
4. CPCSEA Guidelines.
   A Handbook of Applied Statistics in Pharmacology, Katsumi Kobayashi and K. Sadasivan Pillai. CRC Press, Taylor & Francis Group.