CENTRAL UNIVERSITY OF PUNJAB, BATHINDA

Master of Pharmacy
(Pharmacology)

Session 2020-22

DEPARTMENT OF PHARMACOLOGY

Course structure for M. Pharm. (Pharmacology)
<table>
<thead>
<tr>
<th>Course Code</th>
<th>Name of the course</th>
<th>Credit hours</th>
<th>Credit points</th>
<th>Hrs/wk</th>
<th>Marks</th>
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<tbody>
<tr>
<td>MPL 101T</td>
<td>Modern Pharmaceutical Analytical techniques</td>
<td>4</td>
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<tr>
<td>MPL102T</td>
<td>Advanced Pharmacology- I</td>
<td>4</td>
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<tr>
<td>MPL103T</td>
<td>Pharmacological and Toxicological Screening Methods- I</td>
<td>4</td>
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<tr>
<td>MPL104T</td>
<td>Cellular and Molecular Pharmacology</td>
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<tr>
<td>MPL105P</td>
<td>Pharmacological Practical I (Analytical Instruments Handling, Handling of Laboratory Animals, and Bio-Chemical Analysis)</td>
<td>12</td>
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<td>MPL 201T</td>
<td>Advanced Pharmacology- II</td>
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<td>MPL202T</td>
<td>Pharmacological and Toxicological Screening Methods- II</td>
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<td>MPL203T</td>
<td>Principles of Drug Discovery</td>
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<td>MPL204T</td>
<td>Clinical Research and Pharmacovigilance</td>
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<td>MPL205P</td>
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<td>MRM 301T</td>
<td>Research Methodology &amp; Biostatistics</td>
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<td>MPL302T</td>
<td>Journal club</td>
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<td>MPL303T</td>
<td>Discussion/Presentation (Proposal Presentation)</td>
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<td>MPL599</td>
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<td>MPL401T</td>
<td>Journal club</td>
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*To be evaluated by external expert*
IDC Courses
(Offer by Dept. of Pharmacology)

<table>
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<th>Course Code</th>
<th>Name of the course</th>
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<td>IDC-506</td>
<td>Drug Abuse: Problem, Management and Prevention</td>
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<td>IDC-521</td>
<td>Rational use of Medicines</td>
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**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: Subjective Type Test [25 Marks]

C. End-Term Exam: Subjective Type Test [25 Marks]

D. End-Term Exam: Objective Type Test [25 Marks]

**Evaluation Criteria for Practical Courses**

<table>
<thead>
<tr>
<th>Item</th>
<th>Synopsis</th>
<th>Experiment</th>
<th>Practical Notebook and day to day evaluation</th>
<th>Viva voce</th>
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<tr>
<td>Marks</td>
<td>20</td>
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PHARMACOLOGY (MPL)

MODERN PHARMAECUTICAL 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

   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.

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.


4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:
   a. Thin Layer chromatography
   b. High Performance Thin Layer Chromatography
   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 analysis

Total Hrs: 60
separation and applications of the following:
(a) Paper electrophoresis (b) Gel electrophoresis (c) Capillary electrophoresis (d) Zone electrophoresis (e) Moving boundary electrophoresis (f) Iso-electric focusing
(b) X ray Crystallography: Production of X rays, Different X ray methods, Bragg’s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

   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.
   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
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  

<table>
<thead>
<tr>
<th>Theory</th>
<th>Hrs</th>
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<tbody>
<tr>
<td>1. General Pharmacology</td>
<td>12 Hrs</td>
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<tr>
<td>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.</td>
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<tr>
<td>2. Neurotransmission</td>
<td>12 Hrs</td>
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<tr>
<td>a. General aspects and steps involved in neurotransmission.</td>
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<tr>
<td>b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters – Adrenaline and Acetylcholine).</td>
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<tr>
<td>c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters – histamine, serotonin, dopamine, GABA, glutamate and glycine).</td>
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<tr>
<td>d. Non adrenergic non cholinergic transmission (NAN). Co-transmission</td>
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<tr>
<td>Systemic Pharmacology</td>
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<tr>
<td>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</td>
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<tr>
<td>Autonomic Pharmacology</td>
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<tr>
<td>Parasympatho-mimetics and -lytics, sympahto-mimetics and -lytics, agents affecting neuromuscular junction</td>
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<tr>
<td>3. Central nervous system Pharmacology</td>
<td>12 Hrs</td>
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<td>General and local anesthetics</td>
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<tr>
<td>Sedatives and hypnotics, drugs used to treat anxiety.</td>
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<tr>
<td>Depression, psychosis, mania, epilepsy, neurodegenerative diseases.</td>
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<tr>
<td>Narcotic and non-narcotic analgesics.</td>
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<tr>
<td>4. Cardiovascular Pharmacology</td>
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<tr>
<td>Diuretics, antihypertensives, antiischemics, anti-arrhythmics, drugs for heart failure and hyperlipidemia.</td>
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<tr>
<td>Hematincs, coagulants, anticoagulants, fibrinolytics and anti-platelet drugs</td>
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<tr>
<td>5. Autacoid Pharmacology: The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autacoids. Pharmacology of antihistamines, SHT antagonists.</td>
<td>12 Hrs</td>
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</table>
REFERENCES

# 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

<table>
<thead>
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<tbody>
<tr>
<td>1.</td>
<td>Laboratory Animals</td>
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<tr>
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<td>Common laboratory animals: Description, handling and applications of different species and strains of animals.</td>
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<tr>
<td></td>
<td>Transgenic animals: Production, maintenance and applications Anesthesia and euthanasia of experimental animals.</td>
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<tr>
<td></td>
<td>Maintenance and breeding of laboratory animals.</td>
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<tr>
<td></td>
<td>CPCSEA guidelines to conduct experiments on animals.</td>
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<tr>
<td></td>
<td>Good laboratory practice.</td>
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<tr>
<td></td>
<td>Bioassay-Principle, scope and limitations and methods</td>
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<tr>
<td>2.</td>
<td>Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models.</td>
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<td>General principles of preclinical screening. CNS Pharmacology behavioral and muscle co-ordination, CNS stimulants and depressants, anxiolytics, antipsychotics, anti-epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimer’s and multiple sclerosis, Drugs acting on Autonomic Nervous System.</td>
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<td>5.</td>
<td>Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Immunomodulators, immunosuppressants and immunostimulants</td>
<td>12 Hrs</td>
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</tbody>
</table>

REFERENCES
13. Rodents for Pharmacological Experiments, Dr. Tapan Kumar Chatterjee. 2018 (reprint)
15. G Protein-Coupled Receptor Screening Assays by Duarte Miguel F. Prazeres (Editor), Sofia Aires M. Martins (Editor), 2015.
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

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<tr>
<th>1. Cell biology</th>
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<td>Structure and functions of cell and its organelles</td>
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<tr>
<td>Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing</td>
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<td>Cell cycles and its regulation.</td>
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<td>Cell death — events, regulators, intrinsic and extrinsic pathways of apoptosis.</td>
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<td>Necrosis and autophagy.</td>
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<th>2. Cell signaling</th>
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<td>Intercellular and intracellular signaling pathways.</td>
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<tr>
<td>Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.</td>
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<tr>
<td>Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP₃), NO, and diacylglycerol.</td>
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<tr>
<td>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.</td>
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<th>3. Principles and applications of genomic and proteomic tools</th>
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<td>DNA electrophoresis, PCR (reverse transcription and real time),</td>
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<td>Gene sequencing, micro array technique, SDS page, ELISA and western blotting,</td>
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<td>Recombinant DNA technology and gene therapy</td>
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<td>Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology.</td>
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<tr>
<td>Gene therapy— Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.</td>
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<td>Gene mapping and cloning of disease gene.</td>
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<td>Genetic variation and its role in health, pharmacology</td>
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<td>Polymorphisms affecting drug metabolism</td>
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<td>Genetic variation in drug transporters</td>
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<td>Genetic variation in G protein coupled receptors</td>
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<td>Applications of proteomics science: Genomics, proteomics, metabolomics, function omics, nutrigenomics.</td>
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<td>Immunotherapeutic</td>
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<td>Types of immunotherapeutic, humanization antibody therapy, Immunotherapeutic in</td>
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clinical practice

5. a. Cell culture techniques

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:
PHARMACOLOGICAL PRACTICAL-I
(MPL 105P)

A. ANALYTICAL INSTRUMENTS 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 flurometry
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. HANDLING OF LABORATORY ANIMALS
1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogens and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic 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 Braftord/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).
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
Course Title: Seminar/Assignment

Paper Code: MPL106S

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**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

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<tr>
<th>1. Endocrine Pharmacology</th>
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<tr>
<td>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</td>
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<tr>
<td>2. Chemotherapy</td>
<td>12 Hrs</td>
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<tr>
<td>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.</td>
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<td>3. Chemotherapy</td>
<td>12 Hrs</td>
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<tr>
<td>Drugs used in Protozoal Infections</td>
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<tr>
<td>Drugs used in the treatment of Helminthiasis</td>
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<tr>
<td>Chemotherapy of cancer</td>
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<tr>
<td>Immunopharmacology</td>
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<tr>
<td>Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.</td>
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<td>4. GIT Pharmacology</td>
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<td>Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and Hrs drugs for constipation and irritable bowel syndrome.</td>
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<td>Chronopharmacology</td>
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<td>Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer</td>
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<td>5. Free radicals Pharmacology</td>
<td>12 Hrs</td>
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<td>Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer.</td>
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<td>Protective activity of certain important antioxidant</td>
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<tr>
<td>Recent Advances in Treatment: Alzheimer’s disease, Parkinson’s disease, Cancer, Diabetes mellitus</td>
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REFERENCES
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

<table>
<thead>
<tr>
<th>1. Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice (GLP) History, concept and its importance in drug development</th>
<th>12 Hrs</th>
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</thead>
<tbody>
<tr>
<td>2. Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation &amp; dermal toxicity studies. Test item characterization-importance and methods in regulatory toxicology</td>
<td>12 Hrs</td>
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<tr>
<td>3. Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenicity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and chromosomal aberrations studies) In vivo carcinogenicity studies</td>
<td>12 Hrs</td>
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<tr>
<td>4. IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies- origin, concepts and importance of safety pharmacology. Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies</td>
<td>12 Hrs</td>
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<tr>
<td>5. Engineered nanomaterials, drug delivery, nanotoxicology and regulatory requirements, Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.</td>
<td>12 Hrs</td>
</tr>
</tbody>
</table>

REFERENCES;

6. OECD test guidelines
13. Lippincott Illustrated Reviews: Pharmacology (Lippincotts Illustrated Reviews Pharmacology) by Karen Whalen, 2018
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

<table>
<thead>
<tr>
<th>1. An Overview of modern drug discovery process: Target identification, target validation, lead identification and lead optimization. Economics of drug discovery.</th>
<th>12 Hrs</th>
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<tbody>
<tr>
<td>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.</td>
<td>12 Hrs</td>
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<tr>
<td>2. Lead identification- combination chemistry &amp; High throughput screening, in silico lead discovery techniques, Assay development of hit identification. 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.</td>
<td>12 Hrs</td>
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<tr>
<td>3. Rational Drug Design Traditional vs rational drug design, Methods followed in traditional drug design, high Throughput screening, concepts of rational drug design, Rational Drug design Methods: Structure and Pharmacophore based Approaches. Virtual Screening techniques: Drug likeness screening, concept of pharmacophore mapping and pharmacophore-based screening.</td>
<td>12 Hrs</td>
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<tr>
<td>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. 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</td>
<td>12 Hrs</td>
</tr>
</tbody>
</table>
REFERENCES

3. In Silico Technologies in Drug Target Identification and Validation by Darryl León. Scott Markel, 2006
9. Computational Approaches for the Prediction of pKa Values (QSAR in Environmental and Health Sciences) by George C. Shields and Paul G. Seybold, 2017
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

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<tr>
<td>2. Clinical Trials: Types and Design Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management</td>
<td>12 Hrs</td>
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<tr>
<td>4. Basic aspects, terminologies and establishment of pharmacovigilance History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance</td>
<td>12 Hrs</td>
</tr>
</tbody>
</table>
5. Methods, ADR reporting and tools used in Pharmacovigilance

6. Pharmacoepidemiology, Pharmacoeconomics, safety pharmacology (ICH Guideline)

REFERENCES
1. Ethical Guidelines for Biomedical Research on Human Subjects 2017. Indian Council of Medical Research, New Delhi
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 the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine the strength of unknown sample by interpolation bioassay by using suitable tissue preparation.
5. To determine the strength of unknown sample by bracketing bioassay by using suitable tissue preparation.
6. To determine 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

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

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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 (wilcoxon 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.

REFERENCES:

2. Research Methodology: Methods and Techniques by Kothari, C. R. 2019
9. Biomedical Research from Ideation to Publication by Jagadeesh G., Murthy S., Gupta YK, Prakash A, 2010
Course Title: Journal Club Paper

Code: MPL302T

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Course Title: Discussion/ Presentation (Proposal Presentation)

Paper Code: MPL303T

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Course Title: Research Work

Paper Code: MPL599

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**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

Course Title: Discussion/ Presentation Paper Code:
MPL402T

Course Title: Research Work: MPL599

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:

Software tools
- Tracker
- Chem Draw
- Schrodinger
- Maestro /Autodock, etc.
- Blast
Endnote/reference manager, etc.