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<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>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPL 102T</td>
<td>Advanced Pharmacology-I</td>
<td>4</td>
<td>4</td>
<td>4</td>
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<tr>
<td>MPL 103T</td>
<td>Pharmacological and Toxicological Screening Methods-I</td>
<td>4</td>
<td>4</td>
<td>4</td>
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<tr>
<td>MPL 104T</td>
<td>Cellular and Molecular Pharmacology</td>
<td>4</td>
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<td>MPL 105P</td>
<td>Pharmacology Practical I</td>
<td>12</td>
<td>6</td>
<td>12</td>
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<th>Credit Points</th>
<th>Hrs./wk</th>
<th>Marks</th>
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<tr>
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<td>Advanced Pharmacology II</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
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<tr>
<td>MPL 202T</td>
<td>Pharmacological and Toxicological Screening Methods-II</td>
<td>4</td>
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<tr>
<td>MPL 203T</td>
<td>Principles of Drug Discovery</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPL 204T</td>
<td>Experimental Pharmacology practical- II</td>
<td>4</td>
<td>4</td>
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<tr>
<td>MPL 205P</td>
<td>Pharmacology Practical II</td>
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<td></td>
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Table – 12: Course of study for M. Pharm. III Semester
(Common for All Specializations)

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Credit Hours</th>
<th>Credit Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRM 301T</td>
<td>Research Methodology and Biostatistics*</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>-</td>
<td>Journal club</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>-</td>
<td>Discussion / Presentation</td>
<td>2</td>
<td>2</td>
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<tr>
<td></td>
<td>(Proposal Presentation)</td>
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<td>Research Work</td>
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* Non University Exam

Table – 13: Course of study for M. Pharm. IV Semester
(Common for All Specializations)

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Credit Hours</th>
<th>Credit Points</th>
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<tbody>
<tr>
<td>-</td>
<td>Journal Club</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>-</td>
<td>Research Work</td>
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<td>16</td>
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<tr>
<td>-</td>
<td>Discussion / Final Presentation</td>
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Table – 14: Semester wise credits distribution

<table>
<thead>
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<th>Semester</th>
<th>Credit Points</th>
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<tbody>
<tr>
<td>I</td>
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<tr>
<td>II</td>
<td>26</td>
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<tr>
<td>III</td>
<td>21</td>
</tr>
<tr>
<td>IV</td>
<td>20</td>
</tr>
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</table>

Co-curricular Activities
(Attending Conference, Scientific Presentations and Other Scholarly Activities)

Minimum=02
Maximum=07*

Total Credit Points
Minimum=95
Maximum=100*

*Credit Points for Co-curricular Activities
### Tables – 24: Schemes for internal assessments and end semester examinations
**(Pharmacology-MPL)**

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Internal Assessment</th>
<th>End Semester Exams</th>
<th>Total Marks</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Continuous Mode</td>
<td>Sessional Exams</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Mark</td>
<td>Duration</td>
<td>Mark</td>
</tr>
<tr>
<td>MPL101T</td>
<td>Modern Pharmaceutical Analytical Techniques</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPL102T</td>
<td>Advanced Pharmacology-I</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPL103T</td>
<td>Pharmacological and Toxicological Screening Methods-I</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPL104T</td>
<td>Cellular and Molecular Pharmacology</td>
<td>10</td>
<td>15</td>
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</tr>
<tr>
<td>MPL105P</td>
<td>Experimental Pharmacology - I</td>
<td>20</td>
<td>30</td>
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#### SEMESTER II

<table>
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<tr>
<td>MPL201T</td>
<td>Advanced Pharmacology II</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
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<tr>
<td>MPL102T</td>
<td>Pharmacological and Toxicological Screening Methods-II</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
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<tr>
<td>MPL203T</td>
<td>Principles of Drug Discovery</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPL204T</td>
<td>Clinical research and pharmacovigilance</td>
<td>10</td>
<td>15</td>
<td>1 Hr</td>
</tr>
<tr>
<td>MPL205P</td>
<td>Experimental Pharmacology - II</td>
<td>20</td>
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<td>6 Hrs</td>
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<td>Seminar/Assignment</td>
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<td>-</td>
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</table>

29
PHARMACOLOGY (MPL)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MPL 101T)

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

Objectives
After completion of course student is able to know about,
- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY 60 Hrs
IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.
Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characterestics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

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4 Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:  
j) Thin Layer chromatography  
k) High Performance Thin Layer Chromatography  
l) Ion exchange chromatography  
m) Column chromatography  
n) Gas chromatography  
o) High Performance Liquid chromatography  
p) Ultra High Performance Liquid chromatography  
q) Affinity chromatography  
r) Gel Chromatography  
5 Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:  
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing  
X ray Crystallography: Production of X rays, Different X ray methods, Bragg’s law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.  
Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.
REFERENCES
ADVANCED PHARMACOLOGY - I
(MPL 102T)

Scope
The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved

Objectives
Upon completion of the course the student shall be able to:
- Discuss the pathophysiology and pharmacotherapy of certain diseases
- Explain the mechanism of drug actions at cellular and molecular level
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

THEORY 60 Hrs
1. General Pharmacology 12 Hrs
   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 12 Hrs
   a. General aspects and steps involved in neurotransmission.
   b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).
   c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine).
   d. Non adrenergic non cholinergic transmission (NANC). 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

3 Central nervous system Pharmacology
General and local anesthetics
Sedatives and hypnotics, drugs used to treat anxiety.
Depression, psychosis, mania, epilepsy, neurodegenerative diseases.
Narcotic and non-narcotic analgesics.

4 Cardiovascular Pharmacology
Diuretics, antihypertensives, antiischemias, anti-arrhythmics, Hrs drugs for heart failure and hyperlipidemia.
Hematinics, coagulants, anticoagulants, fibrinolytics and anti-platelet drugs

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

REFERENCES
1. The Pharmacological Basis of Therapeutics, Goodman and Gillman's
3. Basic and Clinical Pharmacology by B.G Katzung
5. Applied biopharmaceautics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
7. Avery Drug Treatment
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
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

1. Laboratory Animals
   - Common laboratory animals: Description, handling and applications of different species and strains of animals.
   - Transgenic animals: Production, maintenance and applications
   - Anaesthesia and euthanasia of experimental animals.
   - Maintenance and breeding of laboratory animals.
   - CPCSEA guidelines to conduct experiments on animals
   - Good laboratory 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.
   - General principles of preclinical screening. CNS Pharmacology: behavioral and muscle co ordination, CNS stimulants and

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

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

5 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

216
REFERENCES
1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
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.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)
CELLULAR AND MOLECULAR PHARMACOLOGY
(MPL 104T)

Scope:
The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

Objectives:
Upon completion of the course, the student shall be able to,
- Explain the receptor signal transduction processes.
- Explain the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques as applicable for pharmacology

THEORY 60 Hrs
1. 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.
2. Cell signaling
   Intercellular and intracellular signaling pathways.
   Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.
   Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol.
   Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.
3 Principles and applications of genomic and proteomic tools
DNA electrophoresis, PCR (reverse transcription and real time),
Gene sequencing, micro array technique, SDS page, ELISA and
western blotting,
Recombinant DNA technology and gene therapy
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
Gene mapping and cloning of disease gene.
Genetic variation and its role in health/ pharmacology
Polymorphisms affecting drug metabolism
Genetic variation in drug transporters
Genetic variation in G protein coupled receptors
Applications of proteomics science: Genomics, proteomics,
metabolomics, functionomics, nutrigenomics
Immunotherapeutics
Types of immunotherapeutics, humanisation antibody therapy,
Immunotherapeutics in clinical practice

5 a. Cell culture techniques
Basic equipments used in cell culture lab. Cell culture media,
various types of cell culture, general procedure for cell cultures;
isolation of cells, subculture, cryopreservation, characterization of
cells and their application.
Principles and applications of cell viability assays, glucose uptake
assay, Calcium influx assays
Principles and applications of flow cytometry
b. Biosimilars

REFERENCES:
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J.
Licinio and M -L. Wong
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson
et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach ) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick
M.Ausuvel et la.
PHARMACOLOGICAL PRACTICAL - I
(MPL 105P)

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

Handling of laboratory animals.

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

220
REFERENCES
1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
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)

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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**  

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<thead>
<tr>
<th>1. Endocrine Pharmacology</th>
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<tbody>
<tr>
<td>Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones</td>
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<tr>
<td>Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids.</td>
<td></td>
</tr>
<tr>
<td>Drugs affecting calcium regulation</td>
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<table>
<thead>
<tr>
<th>2. Chemotherapy</th>
<th>12 Hrs</th>
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</thead>
<tbody>
<tr>
<td>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.</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Chemotherapy</th>
<th>12 Hrs</th>
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</thead>
<tbody>
<tr>
<td>Drugs used in Protozoal Infections</td>
<td></td>
</tr>
<tr>
<td>Drugs used in the treatment of Helminthiasis</td>
<td></td>
</tr>
<tr>
<td>Chemotherapy of cancer</td>
<td></td>
</tr>
<tr>
<td>Immunopharmacology</td>
<td></td>
</tr>
<tr>
<td>Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD.</td>
<td></td>
</tr>
<tr>
<td>Immunosuppressants and Immunostimulants</td>
<td></td>
</tr>
</tbody>
</table>
4 GIT Pharmacology
Antulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation
and irritable bowel syndrome.
Chronopharmacology
Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer

5 Free radicals Pharmacology
Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer.
Protective activity of certain important antioxidant
Recent Advances in Treatment:
Alzheimer’s disease, Parkinson’s disease, Cancer, Diabetes mellitus

REFERENCES
1. The Pharmacological basis of therapeutics- Goodman and Gill man’s
3. Basic and Clinical Pharmacology by B.G -Katzung
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. KD.Tripathi. Essentials of Medical Pharmacology

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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

1. Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) 12 Hrs
   Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y
   OECD principles of Good laboratory practice (GLP)
   History, concept and its importance in drug development

2. Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines. 12 Hrs
   Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.
   Test item characterization- importance and methods in regulatory toxicology studies

3. Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenicity studies (segment II)
   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.

60 Hrs
Safety pharmacology studies- origin, concepts and importance of safety pharmacology.  
Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies

5. Toxicokinetics- Toxicokinetic evaluation in preclinical studies, 12 saturation kinetics Importance and applications of toxicokinetic Hrs studies.  
Alternative methods to animal toxicity testing.

REFERENCES
3. Drugs from discovery to approval by Rick NG.
5. OECD test guidelines.
PRINCIPLES OF DRUG DISCOVERY  
(MPL 203T)

Scope:
The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

Objectives:
Upon completion of the course, the student shall be able to,
• Explain the various stages of drug discovery.
• Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
• Explain various targets for drug discovery.
• Explain various lead seeking method and lead optimization
• Appreciate the importance of the role of computer aided drug design in drug discovery

THEORY 60 Hrs
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- 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
3. Rational Drug Design 12 Hrs

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Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,


5 QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. Hrs 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

REFERENCES
2. Darryl León. Scott Markelln. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
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: 12 Hrs
   Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines
   Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR
   Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process
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

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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


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

5 Methods, ADR reporting and tools used in Pharmacovigilance


6 Pharmacoepidemiology, pharmacoeconomics, safety pharmacology

REFERENCES


PHARMACOLOGICAL PRACTICAL - II
(MPL 205P)

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation.
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation.
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA2 values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial.(3 Nos.)
17. Design of ADR monitoring protocol.
18. In-silico docking studies. (2 Nos.)
19. In-silico pharmacophore based screening.
20. In-silico QSAR studies.
21. ADR reporting

REFERENCES

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
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.
PHARMACOGNOSY (MPG)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
(MPG 101T)

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

Objectives
After completion of course student is able to know,
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY 60 Hrs

   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
   Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
   Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

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 separation and applications of the following:
   a) Paper electrophoresis
   b) Gel electrophoresis
   c) Capillary electrophoresis
   d) Zone electrophoresis
   e) Moving boundary electrophoresis
   f) Iso electric focusing

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


   Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and
cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

REFERENCES