### Table – 10: Course of study for (Pharmacology)

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Course</th>
<th>Credit Hours</th>
<th>Credit Points</th>
<th>Hrs./wk</th>
<th>Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPL 101T</td>
<td>Modern Pharmaceutical Analytical Techniques</td>
<td>4</td>
<td>4</td>
<td>4</td>
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<tr>
<td>MPL 102T</td>
<td>Advanced Pharmacology-I</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>
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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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<tr>
<td></td>
<td>Seminar/Assignment</td>
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<td>4</td>
<td>7</td>
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</tr>
<tr>
<td></td>
<td>Total</td>
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<td>26</td>
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<td>650</td>
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### Semester II

<table>
<thead>
<tr>
<th>Course Code</th>
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<th>Credit Hours</th>
<th>Credit Points</th>
<th>Hrs./wk</th>
<th>Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPL 201T</td>
<td>Advanced Pharmacology II</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPL 202T</td>
<td>Pharmacological and Toxicological Screening Methods-II</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
</tr>
<tr>
<td>MPL 203T</td>
<td>Principles of Drug Discovery</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>100</td>
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<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>
<td>Seminar/Assignment</td>
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<td>4</td>
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<td>100</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>35</td>
<td>26</td>
<td>35</td>
<td>650</td>
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</tbody>
</table>
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>
</tr>
<tr>
<td></td>
<td>(Proposal Presentation)</td>
<td>28</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>Research Work</td>
<td>28</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>35</td>
<td>21</td>
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</table>

* 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>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Journal Club</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Research Work</td>
<td>31</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>Discussion/Final Presentation</td>
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<td>3</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>35</td>
<td>20</td>
</tr>
</tbody>
</table>

Table – 14: Semester wise credits distribution

<table>
<thead>
<tr>
<th>Semester</th>
<th>Credit Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>26</td>
</tr>
<tr>
<td>II</td>
<td>26</td>
</tr>
<tr>
<td>III</td>
<td>21</td>
</tr>
<tr>
<td>IV</td>
<td>20</td>
</tr>
<tr>
<td>Co-curricular Activities (Attending Conference, Scientific Presentations and Other Scholarly Activities)</td>
<td>Minimum=02 Maximum=07*</td>
</tr>
<tr>
<td>Total Credit Points</td>
<td>Minimum=95 Maximum=100*</td>
</tr>
</tbody>
</table>

*Credit Points for Co-curricular Activities
ADVANCED PHARMACOLOGY - II
(MPL 201T)

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

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

THEORY 60 Hrs

1. Endocrine Pharmacology 12
   Molecular and cellular mechanism of action of hormones such as growth hormone,
   prolactin, thyroid, insulin and sex hormones
   Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids
   Drugs affecting calcium regulation

2. Chemotherapy 12
   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.

3. Chemotherapy 12
   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

222
4 GIT Pharmacology
Antulcer drugs, Prokinetics, antiemetics, anti-diarrheals and Hrs
drugs for constipation
and irritable bowel syndrome.
Chronopharmacology
Biological and circadian rhythms, applications of chronotherapy in
various diseases like
cardiovascular disease, diabetes, asthma and peptic ulcer

5 Free radicals Pharmacology
Generation of free radicals, role of free radicals in etiopathology of
Hrs
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
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
6. Text book 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, 9th Ed. (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. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy
    by David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W,
    Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers

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

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

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

224
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
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  

226
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. 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 Markelih. 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:
Origin and Principles of International Conference on Hrs
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
Experimental Study- RCT and Non RCT, Hrs
Observation Study: Cohort, Case Control, Cross sectional
Clinical Trial Study Team
Roles and responsibilities of Clinical Trial Personnel: Investigator,
Study Coordinator, Sponsor, Contract Research Organization and its management
3 Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT

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, pharmacoconomics, safety pharmacology

REFERENCES

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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.

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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, 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.

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.