



# SYLLABUS

<b>Course Title</b>	<b>ADVANCED PHARMACOLOGY – II</b>	
<b>Course Code</b>	MPL201T	
<b>Course Credit</b>	Lecture	4
	Tutorial	0
	Total	4
<b>Course Objectives</b>		
<p>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.</p>		
<b>Detailed Syllabus: (Total Hours = 60)</b>		
<b>Sr. No.</b>	<b>Name of Chapter &amp; Details</b>	<b>Hours Allotted</b>
<b>1</b>	<p><b>Endocrine Pharmacology</b>  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.</p>	<b>12</b>
<b>2</b>	<p><b>Chemotherapy</b>  Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as <math>\beta</math>-lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.</p>	<b>12</b>

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

**Instructional Method and Pedagogy:**

- Lectures will be conducted with the aid of multi-media projector, black board, OHP etc.
- Specific discussion questions will be assigned each week. It is important that everyone participate in the discussion.
- Unit Review Quizzes will measure the student's understanding of the material.

**Students Learning Outcomes:**

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.

#### **Reference Books:**

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
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
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, 9<sup>th</sup> 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

#### **Additional Resources**

Latest information are available from scientific journals available in library and on websites.



# SYLLABUS

<b>Course Title</b>	<b>PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II</b>	
<b>Course Code</b>	MPL202T	
<b>Course Credit</b>	Lecture	4
	Tutorial	0
	Total	4
<b>Course Objectives</b>		
<p>This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug &amp; new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.</p>		
<b>Detailed Syllabus: (Total Hours = 60)</b>		
<b>Sr. No.</b>	<b>Name of Chapter &amp; Details</b>	<b>Hours Allotted</b>
<b>1</b>	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.	<b>12</b>
<b>2</b>	Acute, sub-acute and chronic- oral, dermal and inhalation 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	<b>12</b>

<b>3</b>	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	<b>12</b>
<b>4</b>	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.	<b>12</b>
<b>5</b>	Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.	<b>12</b>

#### **Instructional Method and Pedagogy:**

- Lectures will be conducted with the aid of multi-media projector, black board, OHP etc.
- Specific discussion questions will be assigned each week. It is important that everyone participate in the discussion.
- Unit Review Quizzes will measure the student's understanding of the material.

#### **Students Learning Outcomes:**

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.

#### **Reference Books:**

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (<http://www.who.int/tdr/publications/documents/glphandbook.pdf>).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi

3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3<sup>rd</sup> Edition, 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>)

#### **Additional Resources**

Latest information are available from scientific journals available in library and on websites.



# SYLLABUS

<b>Course Title</b>	<b>PRINCIPLES OF DRUG DISCOVERY</b>	
<b>Course Code</b>	MPL203T	
<b>Course Credit</b>	Lecture	4
	Tutorial	0
	Total	4
<b>Course Objectives</b>		
<p>The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process.</p>		
<b>Detailed Syllabus: (Total Hours = 60)</b>		
<b>Sr. No.</b>	<b>Name of Chapter &amp; Details</b>	<b>Hours Allotted</b>
<b>1</b>	<p>An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery.</p> <p>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.</p>	<b>12</b>
<b>2</b>	<p>Lead Identification- combinatorial chemistry &amp; high through puscreening, in silico lead discovery techniques, Assay develop menfor hit identification.</p> <p>Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and</p>	<b>12</b>

	homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction.	
<b>3</b>	<p><b>Rational Drug Design</b></p> <p>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.</p> <p>Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening.</p>	<b>12</b>
<b>4</b>	<p>Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design.</p> <p>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.</p>	<b>12</b>
<b>5</b>	<p>QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods.</p> <p>3D-QSAR approaches like COMFA and COMSIA.</p> <p>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.</p>	<b>12</b>
<b>Instructional Method and Pedagogy:</b>		
<ul style="list-style-type: none"> <li>• Lectures will be conducted with the aid of multi-media projector, black board, OHP etc.</li> <li>• Specific discussion questions will be assigned each week. It is important that everyone participate in the discussion.</li> <li>• Unit Review Quizzes will measure the student’s understanding of the material.</li> </ul>		
<b>Students Learning Outcomes:</b>		
<p>Upon completion of the course, the student shall be able to,</p> <ul style="list-style-type: none"> <li>• Explain the various stages of drug discovery.</li> <li>• Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery.</li> </ul>		



- 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.

#### Reference Books:

1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott Markell. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. 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, 1999.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

#### Additional Resources

Latest information are available from scientific journals available in library and on websites.



# SYLLABUS

<b>Course Title</b>	<b>Clinical Research And Pharmacovigilance</b>	
<b>Course Code</b>	MPL204T	
<b>Course Credit</b>	Lecture	4
	Tutorial	0
	Total	4
<b>Course Objectives</b>		
<p>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.</p>		
<b>Detailed Syllabus: (Total Hours = 60)</b>		
<b>Sr. No.</b>	<b>Name of Chapter &amp; Details</b>	<b>Hours Allotted</b>
<b>1</b>	<p><b>Regulatory Perspectives of Clinical Trials:</b>            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.</p>	<b>12</b>
<b>2</b>	Clinical Trials: Types and Design Experimental Study- RCT and Non RCT,	<b>12</b>

	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.	
<b>3</b>	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.	<b>12</b>
<b>4</b>	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.	<b>12</b>
<b>5</b>	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 mand Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.	<b>12</b>
<b>6</b>	Pharmacoepidemiology, pharmacoconomics, safety pharmacology	<b>12</b>

**Instructional Method and Pedagogy:**

- Lectures will be conducted with the aid of multi-media projector, black board, OHP etc.
- Specific discussion questions will be assigned each week. It is important that everyone participate in the discussion.

- Unit Review Quizzes will measure the student's understanding of the material.

### **Students Learning Outcomes:**

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.

### **Reference Books:**

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, 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.

### **Additional Resources**

1. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6; May 1996.

3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. ASHP software.



# SYLLABUS

<b>Course Title</b>	<b>PHARMACOLOGICAL PRACTICAL - II</b>	
<b>Course Code</b>	MPL205P	
<b>Course Credit</b>	Practical	6
	Total	6
<b>Course Objectives</b>		
<p>This subject includes knowledge drug discovery, laboratory development, animal studies, clinical development, and regulatory submission. This lengthy process is necessary only for understanding the target disease but also for providing substantial evidence regarding efficacy and safety of the pharmaceutical compound under investigation prior to regulatory approval.</p>		
<b>Practical Syllabus</b>		
<ol style="list-style-type: none"><li>1. To record the DRC of agonist using suitable isolated tissues preparation.</li><li>2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.</li><li>3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.</li><li>4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation</li><li>5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation</li><li>6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.</li></ol>		

7. Estimation of PA<sub>2</sub> 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

#### **Instructional Method and Pedagogy:**

- Practical will be conducted with practical hand on various animal models and instruments like ECG, Blood pressure monitoring device etc.
- Study questions based on course content will be given to the students at the end of each practical and will be evaluated at regular interval.
- Surprise tests/Quizzes/Tutorials will be conducted.

#### **Students Learning Outcomes:**

At the completion of the course students should be able to:

- Understand the basic principles, working and applications of preclinical toxicology.

- Understand various international guideline for toxicity and drug discovery process.

#### **Reference Books:**

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

#### **Additional Resources**

1. Indian Pharmacopoeia
2. British Pharmacopoeia
3. U.S. Pharmacopoeia
4. European Pharmacopoeia
5. Korean Pharmacopoeia
6. Chinese Pharmacopoeia
7. Japanese Pharmacopoeia