M. Pharm. (Pharmacology) (1st Year)

Total Contact Hours = 34 Total Marks = 600 Total Credits = 25

SEMESTER 1st		Contact Hrs			Marks			Credits
Subject Code	**Subject Name**	**L**	**T**	**P**	**Int.**	**Ext.**	**Total**	
MPHA2- 101	Systematic Pharmacology	3	1	-	40	60	100	4
MPHA2- 102	Drug Therapy and Pharmacotherapeutics	3	1	-	40	60	100	4
MPHA2- 103	Drug Evaluation and Advanced Pharmacological	3	1	-	40	60	100	4
MPHA2- 104	Basics of Pharmaceutical Research - I	3	1	-	40	60	100	4
MPHA2-105	Pharmacology Laboratory - I	-	-	14	60	40	100	7
MPHA2- 106	Seminar	-	-	4	100	-	100	2
Total	**Theory = 5 Lab = 1**	**12**	**4**	**18**	**320**	**280**	**600**	**25**

Total Contact Hours = 32 Total Marks = 600 Total Credits = 26

SEMESTER 2nd		Contact Hrs			Marks			Credits
Subject Code	**Subject Name**	**L**	**T**	**P**	**Int.**	**Ext.**	**Total**	
MPHA2 –207	Cellular and Molecular Pharmacology	4	-	-	40	60	100	4
MPHA2 – 208	Pharmacological and Toxicological Screening Methods	4	-	-	40	60	100	4
MPHA2 – 209	Principles of Drug Discovery	4	-	-	40	60	100	4
MPHA2 – 210	Clinical Research and Pharmacovigilance	4	-	-	40	60	100	4
MPHA2 - 211	Pharmacology Practical - II	-	-	12	60	40	100	6
MPHA2 - 212	Seminar/ Assignment	-	4	-	100	-	100	4
Total	**Theory = 4 Lab = 1 Seminar =1**	**16**	**4**	**12**	**320**	**280**	**600**	**26**

Overall

Semester	Marks	Credits
1st	600	25
2nd	600	26
Total	**1200**	**51**

SYSTEMATIC PHARMACOLOGY

Subject Code – MPHA2 -101 **L T P C** **Duration – 45 Hrs**
3 1 0 4

UNIT-I (12 Hrs)

Basic Principles of Pharmacology: Mechanisms of Drug Action, Membrane Transporters and Drug Response, Adverse Drug Reactions.

Pharmacology of The Autonomic Nervous System:

1. Physiology of Autonomic Nervous System
2. Muscarinic Receptor Agonists and Antagonists
3. Anticholinesterase Agents
4. Agents Acting at Neuromuscular Junction and Autonomic Ganglia
5. Adrenergic Agonists and Antagonists
6. 5-Hydroxytryptamine Receptor Agonists and Antagonists

UNIT- II (15 Hrs)

Drugs Acting on Cardiovascular System

1. Diuretics
2. Vasopressin and Other Agents Affecting the renal conservation of water
3. Renin, Angiotensin, and Their Modulators
4. Calcium Channel Blockers

Pharmacology of Autacoids

1. Histamine, Bradykinin, and Their antagonists
2. Lipid Derived Autacoids: Eicosanoids and Platelet Activating Factor

Analgesic, Antipyretic, and Anti-inflammatory Agents Immunosuppressants, Tolerogens, and Immunostimulants

UNIT-III (10 Hrs)

Drugs Acting on the Central Nervous System

1. Neurotransmission in Central Nervous System
2. General Anesthetics
3. Local Anesthetics
4. Hypnotics and Sedatives
5. Opioid Analgesics
6. Pharmacology of Ethanol
7. Drug Addiction and Drug Abuse

UNIT-IV (8 Hrs)

Pharmacology of Chemotherapeutic and Antimicrobial Agents

1. General Considerations of Antimicrobial Therapy
2. Sulfonamides, Trimethoprim, Quinolones, Other Related Agents
3. Penicillin, Cephalosporins, and Other Beta-Lactam Antibiotics
4. Aminoglycosides
5. Protein Synthesis Inhibitors and Miscellaneous Antibacterial Agents
6. Antifungal Agents
7. Antiviral Agents (Non-Retroviral)

Hormones and their Antagonists

1. Pituitary Hormones and Their Hypothalamic Releasing Factors
2. Thyroid and Antithyroid Drugs
3. Estrogens and Progestins
4. Androgens
5. Adrenocortical Steroids and Their Synthetic Analogs, Inhibitors of Synthesis and Actions of Adrenocortical Hormones
6. Agents Affecting Mineral Ion Homeostasis and Bone Turnover

Recommended Books

1. Goodman and Gilman, 'The Pharmacological Basis of Therapeutics', Joel G. Hardman, 11th Edn.
2. Lee E. Limbird, Alfred G. Gilman (eds.). International Edition, The McGraw Hill Companies, Inc., **2006.**
3. H.P. Rang and M.M. Dale, 'Pharmacology', 7th Edn., Churchill Livingstone,
4. B.G. Katzung, 'Basic and Clinical Pharmacology', 9th Edn., McGraw-Hill Medical.

DRUG THERAPY AND PHARMACOTHERAPEUTICS

Subject Code – MPHA2 -102 **L T P C** **Duration – 45 Hrs**

3 1 0 4

UNIT-I (4 Hrs)

Basic Principles of Clinical Pharmacology: Monitoring of Drug Therapy, Patient Compliance, Principles of Paediatric and Geriatric Pharmacology, Drug Therapy in Pregnant and Lactating Mothers

UNIT-II (10 Hrs)

Drug Therapy of Cardiovascular Disorders: Pathophysiology and Drug Therapy of: Congestive Cardiac Failure, Hypertension, Cardiac Arrhythmias, Hyperlipidaemia, Ischemic Heart Disease and Atherosclerosis.

UNIT-III (15 Hrs)

Drug Therapy of Neurological Disorders: Pathophysiology and Drug Therapy of Epilepsy, Parkinson's Disease, Migraine and Myasthenia Gravis.

Drug Therapy of Psychiatric Disorders: Pathophysiology and Drug Therapy of Anxiety, Schizophrenia, Alzheimer's Disease, Mood and Sleep Disorders.

Drug Therapy of Endocrine Disorders: Pathophysiology and Drug Therapy of Diabetes Mellitus, Contraception, and Infertility.

Drug Therapy of Inflammatory Disorders: Biology of Inflammation, Pathophysiology and Drug Therapy of Osteoarthritis, Rheumatoid Arthritis and Gout

UNIT-IV (14 Hrs)

Drug Therapy of Respiratory Diseases: Pathophysiology and Drug Therapy of Asthma.

Drug Therapy of Gastrointestinal Diseases: Pathophysiology and Drug Therapy of Peptic ulcers, Emesis and Inflammatory Bowel Disease.

Drug Therapy of Metabolic and Sexual Disorders: Pathophysiology and Drug Therapy of Obesity and Erectile Dysfunction

Drug Therapy of Infectious Diseases: Pathophysiology and Drug Therapy of Tuberculosis, Leprosy, HIV and Related Opportunistic Infections, Malaria, Amoebiasis, and Helminth Infections.

Recommended Books

1. J.T. Dipiro, R.L. Talbert, G.C. Yee, G.R. Matzke, B.G. Wells, L. Michael Posey (eds.), 'Pharmacotherapy: A Pathophysiologic Approach', 6th Edn., The McGraw Hill Companies, Inc., **2005.**
2. E.T. Herfindal and D.R Gourley, 7th Edn., 'Therapeutics: Drug and Disease Management', Lippincott Williams & Wilkins, USA, **2000.**
3. T.M. Speight and NHG Holford (ed.), 'Avery's Drug Treatment: Principals and Practice of Clinical Pharmacology and Therapeutics', 4th Edn,, ADIS Press, Sydney, Australia, **1997.**
4. Dennis L. Kasper, Eugene Braunwald, Anthony S. Fauci, Stephen L. Hauser, Dan L. Longo, J. Larry Jameson, and Kurt J. Isselbacher, (Eds.), 'Harrison's Principles of Internal Medicine', 16th Edn,, McGraw Hill Companies, Inc., **2004.**

DRUG EVALUATION AND ADVANCED PHARMACOLOGICAL TECHNIQUES

Subject Code – MPHA2-103 **L T P C** **Duration - 45 Hrs**

3 1 0 4

UNIT-I (8 Hrs)

Drug Discovery: Strategies and Approaches Employed in Drug Discovery. Basic Concept of Combinatorial Chemistry, High Throughput Screening, Cell Lines and Their Application in

Drug Discovery, Transgenic Animal Models in the Development of New Drugs.

Receptor-Radio Ligand Binding Assays: General Principles and Techniques of Radio Ligand Binding Assays. Specific Assay Design for Adrenoceptors, Dopamine Receptors, Histamine Receptors, GABA and Benzodiazepine Receptors

UNIT-II (11 Hrs)

Pharmacological Techniques to Evaluate the Following Class of Drugs

1. Antihypertensive agents
2. Antianginal agents
3. Antiarrhythmic agents and agents used in sudden cardiac death
4. Drugs used in cardiac failure and cardiomyopathies
5. Drugs used in hyperlipidaemia and atherosclerosis
6. Anti-infarct agents
7. Antiplatelet and thrombolytic agents

UNIT-III (10 Hrs)

Pharmacological Techniques to Evaluate the Following Class of Drugs

1. Antiepileptics
2. Antiparkinsonian Agents
3. Antimigraine Agents
4. Antianxiety Agents and drugs used in mood and sleep disorders
5. Antipsychotics
6. Drugs used in Alzheimer's disease
7. Local anesthetics

UNIT-IV (15 Hrs)

Pharmacological Techniques to Evaluate the Following Class of Drugs

1. Skeletal Muscle Relaxants and Neuromuscular Blockers
2. Antidiabetic Agents
3. Antifertility Agents
4. Analgesics and Drugs Used in Arthritis and Neuropathic Pain
5. Anti-Inflammatory Agents

Pharmacological Techniques to Evaluate the Following Class of Drugs

1. Antiasthmatic Agents
2. Antiulcer Agents
3. Antiemetics
4. Hepatoprotective Agents
5. Antiobesity Agents
6. Drugs Used in Erectile Dysfunction

Recommended Books

1. H.G. Vogel (ed), 'Drug Discovery and Evaluation-Pharmacological Assays', Springer Verlag, Berlin, Germany, **2002.**

2. M.N. Ghosh, 'Fundamentals of Experimental Pharmacology', Scientific Book Agency, Calcutta, India, **1984.**
3. D.R. Laurence and A.L. Bacharach (eds), Vol. 1 and 2, 'Evaluation of Drug Activities: Pharmacometerics', Academic Press, London, U.K., **1964.**
4. David R. Gross, 'Animal Models in Cardiovascular Research', Kluwer Academic Publishers, London, U.K., **1994**.

BASICS OF PHARMACEUTICAL RESEARCH - I

Subject Code – MPHA2-104 **L T P C** **Duration – 45 Hrs**
3 1 0 4

UNIT-I (8 Hrs)

Drug Design and Discovery: Stages of Drug Discovery, Discovery of Lead Compounds, Pharmacophore Identification and Structure Modification, Physicochemical Alterations, Quantitative Structure Activity Relationship, High Throuput Screening, Acute, Sub-Acute and Chronic Studies, In-Vivo and In –Vitro Studies, Introduction to Preclinical and Clinical Trials, Toxicological Studies, FDA Review Process and Approval.

UNIT-II (9 Hrs)

Good Laboratory Practice: Scope of GLP, Definitions, Current GLP in manufacturing, responsibilities. General provision, organization and Personnel, Building and Facilities, Equipment, Control of Components and Drug product, Laboratory and Control of Records and Reports, Non-clinical Testing, Controls on Animal House, Report Preparation and Documentation. Application of Computers in Quality Control Laboratory.

Good Clinical Practices: Introduction, Regulatory perspectives, Provisions, Documentation.

UNIT-III (16 Hrs)

Principles of Experimental Pharmacology: Common Laboratory Animals in Pharmacological Research, Limitations of Animal Tests, Alternatives to Animal Use, Anaesthetics used in Laboratory Animals, Some Standard Techniques Used in Laboratory Animals, Euthanasia of Experimental Animals. Regulations for the Care and Use of Laboratory Animals, CPCSEA, OECD Guidelines

Analytical Method Validation: General Principles, Validation of Analytical and Bio-analytical Method as per ICH Guidelines.

Calibration and Qualification of Analytical Instruments: Electronic Balance, pH Meter, UV-Visible Spectrophotometer, FTIR, GC, HPLC, HPTLC, Disintegration and Dissolution Test Apparatus. **Qualification of Glassware:** Volumetric Flask, Pipette, Beakers and Burette

UNIT-IV (12 Hrs)

Methods in Material Characterization - Particle dimensions: Particle Size and Powder Surface Area, Particle Shape and Surface Morphology.

Characterization of Solid State Structure: Spectroscopy in Pharmaceutical Analysis, X-Ray

Diffraction, Solid-State Nuclear Magnetic Resonance, Vibrational Spectroscopy, Calorimetry in Pharmaceutical Analysis, Water Vapour Sorption, Electron and Confocal Microscopy, Density Measurements.

Thermal Methods of Analysis: Theory, Instrumentation and Applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA)

X-Ray Diffraction Methods: Introduction, Generation of X-Rays, X-Ray Diffraction, Bragg's Law, X-Ray Powder Diffraction, Interpretation of Diffraction Patterns and Applications.

Recommended Books

1. Wolff M.E. Burger, 'Medicinal Chemistry and Drug Discovery- Principle and Practice', John Wiley and Sons, New York.
2. R. Franke, 'Theoretical Drug Design Methods', Vol. VII, Elsevier, New York.
3. R.B. Silverman, 'The Organic Chemistry of Drug Design and Action', Academic Press Inc., San Diego, USA.
4. P.I. Good, 'A Managers Guide to Design and Conduct of Clinical Trials', Wiley-Liss, Hobokem, U.S.A., **2002.**
5. A.C. Cartwright and B.R. Matthews (eds.) 'International Pharmaceutical Product Registration', Elis Horwood, New York, U.S.A., **1994.**
6. H.G. Vogel (ed), 'Drug Discovery and Evaluation-Pharmacological Assays', 2nd Edn., Springer Verlag, Berlin, Germany, **2002**.
7. M.N. Ghosh, 'Fundamentals of Experimental Pharmacology', 2nd Edn., Scientific Book Agency, Calcutta, India, **1984.**
8. Sandy Weinberg 'Good Laboratory Practices, Drugs and Pharm. Sci. Series', Marcel Dekker Inc. Vol. 129
9. 'Spectrometric Identification of Organic Compounds', Robert M. Silverstein, 6th Edn., Wiley & Sons Publication,
10. Donglass A. Skoog, Holler, Nieman, 'Principles of Instrumental Analysis', Thomson & Brooks Cole Publication.
11. Hobert H. Willard, 'Instrumental Methods of Analysis', 7th Edn., CBS Publication.
12. Gary D. Christian, 'Analytical Chemistry', 6th Edn., Wiley & Sons Publication,
13. H. Beckett, J.B. Stenlake, 'Practical Pharmaceutical Chemistry', Volume I & II', 4th Edn., CBS Publications,
14. Skoog, West, Holler and Crouch, 'Fundamentals of Analytical Chemistry', 8th Edn., Thomson & Brooks Cole Publication.

PHARMACOLOGY LABORATORY - I

Subject Code – MPHA2-105 **L T P C**
0 0 14 7

1. Experiments to Study Pharmacology of Receptors (Competitive and Non-Competitive Antagonists). Experiments to Calculate pA_2 and pA_{10} Using Isolated Rectus Abdominal Muscle of Rat, Vas Deferens, Muscle of Rat, Rat Colon, and Rat Fundus Preparations.
2. Experiments in Intact Animals to Evaluate Local anaesthetics, Mydriatics, Miotics, Analgesics, Anti-Inflammatory Agents, Hypnotics, Antianxiety Agents, Antiepileptic Agents, Antidepressants, Antipsychotics, Antiparkinsonian Agents, Nootropics, and Antiulcer Agents
3. Design and Statistical Analysis of Experimental Data Using Student T-Test, One Way ANOVA etc.

Recommended Books

1. M.N. Ghosh, 'Fundamentals of Experimental Pharmacology', 2nd & 3rd Edn., Scientific Book Agency, Calcutta, India, **1984, 2005**.
2. Staff of the Department of Pharmacology, University of Edinburgh (Ed.). 'Pharmacological Experiments on Isolated Preparations', 2nd Edn., Edinburgh and London, E and S Livingstone, **1970**.
3. H.G. Vogel (Ed), 'Drug Discovery and Evaluation-Pharmacological Assays', Springer Verlag, Berlin, Germany, **2002**.
4. W.W. Daniel, 'Biostatistics: A Foundation for Analysis in The Health Sciences', 7th Edn., John Wiley & Sons, Inc., India, **2000**.
5. S.P. Gupta, 'Statistical Methods', 31st Edn., Sultan Chand & Sons, India, **2003.**

SEMINAR

Subject Code – MPHA2-106 **L T P C**
0 0 4 2

1. Introduction, Information and Retrieval Systems.
2. Writing Assignments and Term Papers.
3. Reading Research Papers.
4. Organization and Presentation of Scientific Material, Research Work, Dissertations, patents etc.
5. Skills in Oral and Technical Presentations.

Each student has to present at least three seminars during the semester.

CELLULAR AND MOLECULAR PHARMACOLOGY

Subject Code – MPHA2 –207 **L T P C** **Duration – 50 Hrs**
4 0 0 4

Scope

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

Objectives

Upon completion of 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

UNIT-I (12 Hrs)

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.

UNIT- II (12 Hrs)

Cell Signalling

- Intercellular and intracellular signalling pathways.
- Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.
- Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol. Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

UNIT-III (12 Hrs)

- 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.

UNIT-IV (14 Hrs)

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
- Immunotherapeutic, Types of immunotherapeutic, humanisation antibody therapy, Immunotherapeutic in clinical practice

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
- Biosimilars

Recommended Books

1. Geoffrey M. Cooper, 'The Cell, A Molecular Approach'.
2. 'Pharmacogenomics: The Search for Individualized Therapies'. Edited by J. Licinio and M -L. Wong.
3. Ralph A. et.al, 'Handbook of Cell Signalling', 2nd Edn..
4. John Dickenson et.al, 'Molecular Pharmacology: From DNA to Drug Discovery'.
5. Cheril D. Helgason and Cindy L. Miller, 'Basic Cell Culture Protocols'.
6. J.M. Davis (Editor), 'Basic Cell Culture (Practical Approach)'.
7. John R. Masters, 'Animal Cell Culture: A Practical Approach'.
8. Frederick M. Ausuvel et al, 'Current Protocols in Molecular Biology' Vol I to VI.

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS

Subject Code – MPHA2 -208 **L T P C** **Duration – 50 Hrs**

4 0 0 4

Scope

This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

Objectives

Upon completion of the course, the student shall be able to,

- 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.

UNIT-I (14 Hrs)

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

UNIT-II (12 Hrs)

- 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

UNIT-III (12 Hrs)

- 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.

UNIT-IV (10 Hrs)

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

Recommended Books

1. 'Hand book on GLP, Quality Practices for regulated non-clinical Research and Development ', (http://www.who.int/tdr/publications/documents/glp-handbook.pdf).
2. Schedule Y. Guideline: Drugs and Cosmetics (second amendment) Rules, 2005, Ministry of Health and Family Welfare (department of health), New Delhi.
3. N.G. Rick, 'Drugs from Discovery to Approval'.

4. Animal Models in Toxicology, 3rd Edn., Lower and Bryan.
5. OECD Test Guidelines.
6. Karen E. Stine, Thomas M. Brown, 'Principles of Toxicology'.
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)

PRINCIPLES OF DRUG DISCOVERY

Subject Code – MPHA2-209 **L T P C** **Duration - 50 Hrs**

4 0 0 4

Scope

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

Objectives

Upon completion of 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

UNIT-I (12 Hrs)

An overview of Modern Drug Discovery Process

- Target identification, target validation, lead identification and lead Optimization.
- Economics of drug discovery.
- Target Discovery and Validation-Role of Genomics, Proteomics and Bioinformatics.
- Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins.
- Role of transgenic animals in target validation.

UNIT-II (12 Hrs)

- **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 modelling methods. Application of NMR and X-ray crystallography in protein structure prediction

UNIT-III (12 Hrs)

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,

UNIT-IV (14 Hrs)

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

Recommended Books

1. Mouldy Sioud, 'Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options', Humana Press Inc., **2007.**
2. Darryl León. Scott MarkelIn, 'Silico Technologies in Drug Target Identification and Validation', Taylor and Francis Group, LLC, **2006.**
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', Wiley-VCH.
5. Klaus Gubernator and Hans-Joachim Böhm, 'Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry', 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.

CLINICAL RESEARCH AND PHARMACOVIGILANCE

Subject Code – MPHA2-210 **L T P C** **Duration – 50 Hrs**
4 0 0 4

Scope

- This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance.
- It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials.
- This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data.
- It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

Objectives

Upon completion of the course, the student shall be able to,

- 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

UNIT-I (11 Hrs)

Regulatory Perspectives of Clinical Trials

- Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines
- Ethical Committee: Institutional Review Board, 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

UNIT-II (13 Hrs)

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
- 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.

UNIT-III (13 Hrs)

- 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

UNIT-IV (12 Hrs)

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 and Reporting to regulatory authorities,
- Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow,
- Statistical methods for evaluating medication safety data.
- Pharmacoepidemiology, Pharmacoeconomics, Safety Pharmacology

Recommended Books

1. 'Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India', Ministry of Health, New Delhi, **2001.**
2. 'Ethical Guidelines for Biomedical Research on Human Subjects', Indian Council of Medical Research, New Delhi, **2000.**

3. 'Textbook of Clinical Trials', edited by David Machin, Simon Day and Sylvan Green, John Wiley and Sons, **2005.**
4. R.K. Rondels, S.A. Varley, C.F. Webbs, 'Clinical Data Management', Wiley Publications, **2000**.
5. Julia Lloyd and Ann Raven, 'Handbook of Clinical Research', Churchill Livingstone.
6. Giovanna di Ignazio, Di Giovanna and Haynes, 'Principles of Clinical Research'.

PHARMACOLOGY LABORATORY - II

Subject Code – MPHA2-210 **L T P C**
0 0 12 6

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

Recommended Books

1. M.N. Ghosh, 'Fundamentals of experimental Pharmacology'.
2. S.K. Kulakarni, 'Hand book of Experimental Pharmacology'.
3. Ian Kitchen, 'Text book of in-vitro practical Pharmacology'.
4. Atta-ur-Rahman, Iqbal choudhary and William Thomsen, 'Bioassay Techniques for Drug Development'.

5. Leon Shargel and Andrew B.C.Yu, 'Applied biopharmaceutics and Pharmacokinetics'.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.

SEMINAR/ASSIGNMENTS

Subject Code – MPHA2-211 **L T P C**
0 4 0 4

1. Introduction, Information and Retrieval Systems.
2. Writing Assignments and Term Papers.
3. Reading Research Papers.
4. Organization and Presentation of Scientific Material, Research Work, Dissertations, patents etc.
5. Skills in Oral and Technical Presentations.
6. Tutorials related to subject taught

Each student has to present at least three seminars during the semester.