SEVEN HILLS COLLEGE OF PHARMACY
[AUTONOMOUS]
Venkatramapuram, **TIRUPATI** - 517 561, A.P, INDIA
Approved by PCI, New Delhi, Govt. of A.P.
Awarding University: JNT University Anantapur – Ananthapuramu
Recognized by UGC Under Sections 2(f) & 12(B) of UGC Act 1956

SHCP R23 Syllabus – 2023

M.Pharmacy – Pharmacology
Pre-Ph.D. Course Work
(2023-24 Admitted Batch)

COURSE STRUCTURE AND SYLLABUS
Effective from Academic Year 2023-24
(2023-24 Admitted Batch)

I Semester

S. No	Course Code	Subjects	Type of Course (C/CBS)	Contact (Hrs/ Week)	Credits	IA	ESE
1	23S01102	Advanced Pharmacology-I	C	3L+1T	4	30S+10Obj	60
2	23S01103	Pharmacological and Toxicological ScreeningMethods-I	C	3L+1T	4	30S+10Obj	60
3	23S01104	Cellular and Molecular Pharmacology	C	3L+1T	4	30S+10Obj	60

II Semester

S. No	Course Code	Subject	Type of Course (C/CBS)	Contact (Hrs/ Week)	Credits	IA	ESE
1	23S01201	Advanced Pharmacology II	C	3L+1T	4	30S+10Obj	60
2	23S01202	Pharmacological and Toxicological ScreeningMethods-II	C	3L+1T	4	30S+10Obj	60
3	23S01203	Principles of Drug Discovery	C	3L+1T	4	30S+10Obj	60
4	23S01204	Clinical Research and Pharmacovigilance	C	3L+1T	4	30S+10Obj	60

Course Code	ADVANCED PHARMACOLOGY-I	L	T	P	C
23S01102		4	0	0	4
Semester		**I**			

Course Objectives:

The subject is designed to strengthen the basic knowledge in the field of pharmacology and toimpart 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.

Course Outcomes (CO): 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 treatmentof diseases.

UNIT - I	12hrs	
Self-Study	*Introduction & basic concepts of pharmacokinetics, dynamics and receptors*	

General Pharmacology

a) Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding.

b) Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantification of drug receptors interaction and elicited effects.

UNIT - II	12 hrs	
Self-Study	a. General aspects and steps involved in neurotransmission. *b.* A detailed study on pathophysiology of diseases,	

Neurotransmission

a) Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetylcholine).

b) Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters-histamine, serotonin, dopamine, GABA, glutamate and glycine].

c) Non adrenergic non cholinergic transmission (NANC). Co-transmission.

d) 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.

e) Autonomic Pharmacology: Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction.

UNIT - III	12hrs	
Self-study	*Basics of CNS*	

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

UNIT - IV	12hrs	
Self-Study	*Basics about cardiovascular diseases*	

Cardiovascular Pharmacology

Diuretics, Antidiuretics, antihypertensives, anti-ischemics, anti-arrhythmics, drugs for heart failure andhyperlipidemia. Hematinics, coagulants , anticoagulants, fibrinolytics and antiplatelet drugs.

UNIT - V	12hrs	
Self-Study	*Basics about autocoids, its types*	

Autocoid Pharmacology: The physiological and pathological role of Histamine, Serotonin, Kinins, Prostaglandins Opioid autocoids.
Pharmacology of antihistamines, 5HT antagonists. Nutraceuticals and their importance

Reference Books:

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman‘s
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapyby David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W,Armstrong, Wolters, Kluwer-LippincottWilliams & Wilkins Publishers.
3. Basic and Clinical Pharmacology by B.G Katzung
4. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel andAndrew B.C.Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists.
10. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
11. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastava published by APC Avichal Publishing Company
12. KD. Tripathi. Essentials of Medical Pharmacology.
13. Modern Pharmacology with Clinical Applications, Craig Charles R. & Stitzel Robert E., Lippincott Publishers.
14. Clinical Pharmacokinetics & Pharmacodynamics: Concepts andApplications – Malcolm Rowland and Thomas N.Tozer, Wolters Kluwer, Lippincott Williams & Wilkins Publishers.
15. Applied bio-pharmaceutics and Pharmacokinetics, Pharmacodynamics and Drug metabolism for industrial scientists.
16. Modern Pharmacology, Craig CR. & Stitzel RE, Little Brown & Company.

Course Code	PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I	L	T	P	C
23S01103		4	0	0	4
	Semester	I			

Course Objectives:

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.

Course Outcomes (CO): 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

UNIT - I	12hrs	
Self-Study	*Introduction to bioassay, principles, limitations*	

a) Laboratory Animals: Common laboratory animals: Description, handling and applications of different species and strains of animals.

b) Transgenic animals: Production, maintenance and applications. Anaesthesia and euthanasia of experimental animals.

c) Maintenance and breeding of laboratory animals.

d) CPCSEA guidelines to conduct experiments on animals and Good laboratory practice.

e) Bioassay - Principle, scope and limitations and methods

f) **High throughput screening and their techniques.**

UNIT - II	12 hrs	

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 depressants, anxiolytics, anti-psychotics, anti-epileptics and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

UNIT - III	12hrs	

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

Respiratory Pharmacology: anti-asthmatics, drugs for COPD andanti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyreticagents.

Gastrointestinal drugs: anti ulcer, anti -emetic, antidiarrhealand laxatives.

UNIT - IV	12hrs	
Self-Study	*Basics about cardiovascular diseases, metabolic disorders, cancer*	

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

b) Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal,

antiatherosclerotic agents and diuretics.

c) Drugs for metabolic disorders like anti-diabetic, anti-dyslipidemic agents.

d) Anti-cancer agents. Hepatoprotective screening methods.

e) **Estimation of drugs from complex media like biological fluids, e.g. blood, tissues, CSF etc.**

UNIT - V	12hrs	
Self-Study	*Basics about immunity.*	

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

b) 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.

c) Limitations of animal experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical to humans.

Reference Books:

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
4. Methods in Pharmacology by Arnold Schwartz.
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.
8. Experimental Pharmacology by R.K.Goyal.
9. Preclinical evaluation of new drugs by S.K. Guta
10. Handbook of Experimental Pharmacology, SK.Kulkarni
11. Practical Pharmacology and Clinical Pharmacy, SK.Kulkarni, 3rd Edition.
12. David R.Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer AcademicPublishers, London, UK.
13. Screening Methods in Pharmacology, Robert A.Turner.
14. Rodents for Pharmacological Experiments, Dr.Tapan Kumar chatterjee.
15. Practical Manual of Experimental and Clinical Pharmacology by BikashMedhi (Author),Ajay Prakash (Author)

Course Code	CELL AND MOLECULAR BIOLOGY	L	T	P	C
23S01104		4	0	0	4
	Semester	I			

Course Objectives:

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.

Course Outcomes (CO): 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 discoveryprocess.
- Demonstrate molecular biology techniques as applicable for pharmacology

UNIT - I	12hrs	
Self-Study	Structure and functions of cell and its organelles.	

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. **Apoptosis and its physiological, pharmacological implications and therapeutic prospects.**

UNIT - II	10 hrs	
Self-Study	Intercellular and intracellular signaling pathways.	

Cell signaling: Intercellular and intracellular signaling pathways.
Classification of receptor family and molecular structure ligandgated 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	12hrs	
Self-study	*Basics of CNS*	

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	12hrs	

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.

UNIT - V	14hrs	

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 assay, sPrinciples and applications of flow cytometry

b. Biosimilars

c. **Detection methods • Fluorescence based assay techniques • Chemiluminescence based assay techniques.**

Reference Books:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
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 Dickensonet.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 al.

Course Code	ADVANCED PHARMACOLOGY - II	L	T	P	C
23S01201		4	0	0	4
	Semester	II			

Course Objectives:

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

Course Outcomes (CO): 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 treatmentof diseases

UNIT - I	12hrs	

Endocrine Pharmacology

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

UNIT - II	12 hrs	

Chemotherapy

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.

UNIT - III	12hrs	
Self-study	*Basics of cancer, immunity, inflammation*	

Chemotherapy: Drugs used in Protozoal Infections, Drugs used in the treatment of Helminthiasis,Chemotherapy of cancer.

Immunopharmacology: Cellular and biochemical mediators of inflammation and immuneresponse. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immunosuppressants and Immunostimulants

Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.

UNIT - IV	12hrs	

GIT Pharmacology

Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritablebowel syndrome.

Chronopharmacology

Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer

UNIT - V	14hrs	

Free radicals Pharmacology

Generation of free radicals, role of free radicals in etiopathology of various diseases such asdiabetes, neurodegenerative diseases and cancer.

Protective activity of certain important antioxidant Recent Advances in Treatment: Alzheimer'sdisease, Parkinson's disease, Cancer, Diabetes mellitus

Reference Books:

1. The Pharmacological basis of therapeutics- Goodman and Gill man's
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy byDavid E Golan etal.

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 andAndrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and DrugMetabolism for Industrial Scientists
9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (RobbinsPathology)
10. A Complete Textbook of Medical Pharmacology by Dr. S.K Srivastavapublished by APC Avichal Publishing Company.
11. KD.Tripathi. Essentials of Medical Pharmacology
12. Principles of Pharmacology. The Pathophysiologic basis of drug Therapyby David E Golan, Armen H, Tashjian Jr, Ehrin J,Armstrong, April W,Armstrong, Wolters, Kluwer-LippincottWilliams & Wilkins Publishers

Course Code	PHARMACOLOGICAL AND TOXICOLOGICAL SCREENINGMETHODS-II	L	T	P	C
23S01202		4	0	0	4
Semester		II			

Course Objectives:

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.

Course Outcomes (CO): 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	12hrs	

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

UNIT - II	12 hrs	

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 - III	12hrs	

Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenecity studies (segment II) Genotoxicity studies (Ames Test, in vitro and in vivo Micronucleus and Chromosomal aberrations studies)In vivo carcinogenicity studies

UNIT - IV	12hrs	

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 otherstudies

UNIT - V	12hrs	

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

Reference Books:

1. Hand book on GLP, Quality practices for regulated non-clinical researchand development(http://www.who.int/tdr/publications/documents/glphandbook.pdf).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules,2005, ministry ofhealth and family welfare (department of health) NewDelhi
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd 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 ClinicalTrials and Marketing Authorization forPharmaceuticals (http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

Course Code	PRINCIPLES OF DRUG DISCOVERY	L	T	P	C
23S01203		4	0	0	4
	Semester	II			

Course Objectives:

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

Course Outcomes (CO): 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 drugdiscovery
- 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 12hrs

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, Proteinmicro-arrays, Antisense technologies, siRNAs, antisenseoligo nucleotides, 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 modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

UNIT - III 12hrs

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 12hrs

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

UNIT - V 12hrs

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.

Reference Books:

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 EmergingMolecular Targets and Treatment Options. 2007Humana Press Inc.

2. Darryl León. Scott MarkelIn. 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 NewYork Dordrecht Heidelberg London.

4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles inMedicinal Chemistry. Publisher Wiley-VCH

5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods andPrinciples in Medicinal Chemistry. Publisher Wiley-VCH

6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and PracticalApplications. 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.

Course Code	CLINICAL RESEARCH AND PHARMACOVIGILANCE	L	T	P	C
23S01204		4	0	0	4
	Semester	II			

Course Objectives:

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.

Course Outcomes (CO): 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 inPharmacovigilance

UNIT - I	12hrs	

Regulatory Perspectives of Clinical Trials: 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.

UNIT - II	12 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.

UNIT - III	12hrs	

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 - IV	12hrs	

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 - V	12hrs	

Methods, ADR reporting and tools used in Pharmacovigilance International classification of diseases, International Nonproprietary 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, Vigi Flow, Statistical methods for evaluating medication safety data.

b . Pharmacoepidemiology, pharmacoeconomics, safety pharmacology

Reference Books:

1. Central Drugs Standard Control Organization- Good Clinical Practices,Guidelines for Clinical Trials on Pharmaceutical Products in India. NewDelhi: Ministry of Health;2001.

2. International Conference on Harmonization of Technical requirements forregistration of Pharmaceuticals for human use. ICH Harmonized TripartiteGuideline. 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 SylvanGreen, 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. ChurchillLivingstone.

7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovannaand Haynes.

Course Code	RESEARCH METHODOLOGY AND BIOSTATISTICS	L	T	P	C
23S01301		4	0	0	4
	Semester	III			

Course Objectives: This course will enable students:

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

Course Outcomes (CO): Student will be able to

- Understand research problem formulation.
- Analyze research related information
- Follow research ethics
- Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
- Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasis the need of information about Intellectual Property Right tobe promoted among students in general & engineering in particular.
- Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn
- brings about, economic growth and social benefits.

UNIT - I	Lecture Hrs:10

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	Lecture Hrs:10

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 (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT - III	Lecture Hrs:10

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	Lecture Hrs:9

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		Lecture Hrs:9
Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.		
Suggested Reading		
1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science &engineering students" 2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction"		