JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M. Pharmacy (HOSPITAL AND CLINICAL PHARMACY)

COURSE STRUCTURE AND SYLLABUS Effective from Academic Year 2017-18 Admitted Batch

I Year - I Semester

Category	Course Title	Int.	Ext.	L	Р	С
		marks	marks			
Core Course I	Pharmacotherapeutics-I	25	75	4		4
Core Course II	Clinical Pharmacy Practice	25	75	4		4
Core Course III	Hospital and Community Pharmacy	25	75	4		4
Core Elective I	 Clinical Research and Pharmacovigilance Pharmacoepidemiology and Pharmacoeconomics 	25	75	4		4
Open Elective I	 Pharmaceutical Management Drug Regulatory Affairs Herbal Cosmetics Technology Pharmaceutical Validation Phytochemistry 	25	75	4		4
Laboratory I	Pharmacotherapeutics-I Lab	25	75		6	3
Laboratory II	Clinical Pharmacy Practice Lab	25	75		6	3
Seminar I	Seminar	50			4	2
	Total Credits		-	20	16	28

I Year - II Semester

Category	Course Title	Int.	Ext.	L	Р	С
		marks	marks			
Core Course IV	Clinical Pharmacokinetics and Therapeutic	25	75	4		4
	Drug Monitoring					
Core Course V	Pharmacotherapeutics-II	25	75	4		4
Core Course VI	Principles of Quality use of Medicines	25	75	4		4
Core Elective II	Clinical Toxicology	25	75	4		4
	Advanced Drug Delivery Systems					
Open Elective II	Stability of Drugs and Dosage Forms	25	75	4		4
	Principles of Drug Discovery					
	Biostatistics and Research Methodology					
	Screening Methods in Pharmacology					
	5. Entrepreneurship Management					
Laboratory III	Pharmacotherapeutics-II Lab	25	75		6	3
Laboratory IV	Clinical Pharmacokinetics and Therapeutic	25	75		6	3
	Drug Monitoring Lab					
Seminar II	Seminar	50			4	2
	Total Credits			20	16	28

II Year - I Semester

Course Title	Int. marks	Ext. marks	L	Р	С
Comprehensive Viva-Voce		100			4
Project work Review I	50			24	12
Total Credits				24	16

II Year - II Semester

Course Title	Int.	Ext.	L	Р	С
	marks	marks			
Project work Review II	50			8	4
Project Evaluation (Viva-Voce)		150		16	12
Total Credits				24	16

CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING (Core Course - IV)

Course Objective: This course is designed to enable students to understand the basics principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in altered pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen. Also, it enables students to understand the basic concepts of pharmacogenetics, pharmacometrics for modeling and simulation of pharmacokinetic data.

Course Outcome: Upon completion of this course it is expected that students shall be able to:

- Design the drug dosage regimen for individual patients
- Interpret and correlate the plasma drug concentrations with patients' therapeutic outcomes
- Recommend dosage adjustment for patients with renal/ hepatic impairment
- Recommend dosage adjustment for paediatrics and geriatrics
- Manage pharmacokinetic drug interactions
- Apply pharmacokinetic parameters in clinical settings
- Interpret the impact of genetic polymorphisms of individuals on pharmacokinetics and or pharmacodynamics of drugs
- Do pharmacokinetic modeling for the given data using the principles of pharmacometrics

UNIT I

Introduction to Clinical pharmacokinetics: Compartmental and Non compartmental models, Renal and non-renal clearance, Organ extraction and models of hepatic clearance, Estimation and determinants of bioavailability, Multiple dosing, Calculation of loading and maintenance doses.

Designing of dosage regimens: Determination of dose and dosing intervals, Conversion from intravenous to oral dosing, Nomograms and Tabulations in designing dosage regimen.

UNIT II

Pharmacokinetics of Drug Interaction: Pharmacokinetic drug interactions, Inhibition and Induction of Drug metabolism, Inhibition of Biliary Excretion.

Pharmacogenetics: Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes, Genetic Polymorphism in Drug Transport and Drug Targets, Pharmacogenetics and Pharmacokinetic/Pharmacodynamic considerations.

Introduction to Pharmacometrics: Introduction to Bayesian Theory, Adaptive method or Dosing with feedback, Analysis of Population pharmacokinetic Data.

UNIT III

Non Linier Mixed Effects Modelling: The Structural or Base Model, Modeling Random Effects, Modeling Covariate Relationships, Mixture Model, Estimation Methods, Model Building Techniques, Covariate Screening Methods, Testing the model assumptions, Precision of the parameter estimates and confidence intervals, Model misspecification and violation of the model assumptions, Model Validation, Simulation of dosing regimens and dosing recommendations, Pharmacometrics software.

UNIT IV

Altered Pharmacokinetics: Drug dosing in the elderly, Drug dosing in the paediatrics, Drug dosing in the obese patients, Drug dosing in the pregnancy and lactation, Drug dosing in the renal failure and extracorporeal removal of drugs, Drug dosing in the inhepatic failure.

UNIT V

Therapeutic Drug monitoring: Introduction, Individualization ofdrug dosage regimen (Variability – Genetic, age, weight, diseaseand Interacting drugs), Indications for TDM, Protocol for TDM, Pharmacokinetic/Pharmacodynamic Correlation in drug therapy,

TDM of drugs used in the following conditions:

Cardiovascular disease: Digoxin, Lidocaine, Amiodarone;

Seizure disorders: Phenytoin, Carbamazepine, Sodium Valproate;

Psychiatricconditions: Lithium, Fluoxetine, Amitriptyline;

Organtransplantations: Cyclosporine; Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin; Antibiotics: Vancomycin, Gentamicin, Meropenem.

- 1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. New York: McGraw Hill.
- Peter L. Bonate. Pharmacokinetic Pharmacodynamic Modeling and Simulation. Springer Publications.
- 3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E. Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring. lippincott Williams & Wilkins.
- 4. Steven How-Yan Wong, Irving Sunshine. Handbook of AnalyticalTherapeutic Drug Monitoring and Toxicology. CRC Press, USA.
- 5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press.
- Joseph T. Dipiro, William J. Spruill, William E. Wade, Robert A.Blouin and Jane M. Pruemer Concepts in Clinical Pharmacokinetics. AmericanSociety of Health-System Pharmacists, USA.
- 7. Malcolm Rowland, Thomas N. Tozer .Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. lippincott Williams &Wilkins, USA.
- 8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health system Pharmacists, USA.
- 9. Michael E. Winter. Basic Clinical Pharmacokinetics. lippincott Williams &Wilkins, USA.
- 10. Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. Pharma Book Syndicate, USA.
- 11. Dhillon and Kostrzewski. Clinical pharmacokinetics. Pharmaceutical Press, London.
- 12. John E .Murphy. Clinical Pharmacokinetics. 5th edition. US: AmericanSociety of Health-System Pharmacist, USA.
- 13. Relevant review articles from recent medical and pharmaceutical literature

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD I Year – II Sem M. Pharm (HCP) PHARMACOTHERAPEUTICS – II (Core Course - V)

Course Objective: This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

Course Outcome: Upon completion of this course it is expected that students shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effect/s)

UNIT I

Nervous system: Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer's disease, Neuralgias and Pain pathways and Pain management.

UNIT II

Psychiatric disorders: Schizophrenia, Depression, Anxiety disorders, Sleep disorders, Drug induced psychiatric disorders

Renal system: Acute renal failure, Chronic renal failure, Renal dialysis, Drug induced renal disease

UNIT III

Infectious diseases: General guidelines for the rational use of antibiotics and surgical prophylaxis, Urinary tract infections, Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria, Bacterial endocarditis, Septicemia.

UNIT IV

Infectious diseases: Meningitis, HIV and opportunistic infections, Rheumatic fever, Dengue fever, H1N1, Helmenthiasis, Fungal infections

Gynecological disorders: Dysmenorrhea, Hormone replacement therapy.

UNIT V

Oncology: General principles of cancer chemotherapy, pharmacotherapy of breast cancer, lung cancer, head & neck cancer, hematological malignancies, Management of nausea and vomiting, Palliative care

- 1. Roger and Walker. Clinical Pharmacy and Therapeutics Churchill Livingstone publication.
- 2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach-Appleton & Lange
- 3. Robins SL. Pathologic basis of disease -W. B. Saunders publication
- 4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
- Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
- 6. Chisholm Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-- McGraw Hill Publication
- 7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
- 8. Harrison's. Principles of Internal Medicine McGraw Hill
- 9. Relevant review articles from recent medical and pharmaceutical literature

PRINCIPLES OF QUALITY USE OF MEDICINES (Core Course - VI)

Course Objective: This course is designed to impart basic knowledge and skills that are required to practice quality use of medicines (QUM) in different healthcare settings and also to promote quality use of medicines, in clinical practice, through evidence-based medicine approach.

Outcomes: Upon completion of this course it is expected that students shall be able to:

- Understand the principles of quality use of medicines
- Know the benefits and risks associated with use of medicines
- Understand regulatory aspects of quality use of medicines
- Identify and resolve medication related problems
- Promote quality use of medicines
- Practice evidence-based medicines

UNIT I

Introduction to Quality use of medicines (QUM): Definition and Principles of QUM, Key partners and responsibilities of the partners, Building blocks in QMC, Evaluation process in QMC, Communication in QUM, Cost effective prescribing.

UNIT II

Concepts in QUM Evidence based medicine: Definition, concept of evidence based medicine, Approach and practice of evidence based medicine in clinical settings

Essential drugs: Definition, need, concept of essential drug, National essential drug policy and list Rational drug use: Definition, concept and need for rational drug use, Rational drug prescribing, Role of pharmacist in rational drug use.

UNIT III

QUM in various settings: Hospital settings, Ambulatory care/Residential care, Role of health care professionals in promoting the QUM, Strategies to promote the QUM, Impact of QUM on E-health, integrative medicine and multidisciplinary care.

QUM in special population: Pediatric prescribing, Geriatric prescribing, prescribing in pregnancy and lactation, Prescribing in immune compromised and organ failure patients.

UNIT IV

Regulatory aspects of QUM in India: Regulation including scheduling, Regulation of complementary medicines, Regulation of OTC medicines, Professional responsibility of pharmacist, Role of industry in QUM in medicine development.

UNIT V

Medication errors: Definition, categorization and causes of medication errors, Detection and prevention of medication errors, Role of pharmacist in monitoring and management of medication errors

Pharmacovigilance: Definition, aims and need for pharmacovigilance, Types, predisposing factors and mechanism of adverse drug reactions (ADRs), Detection, reporting and monitoring of ADRs, Causality assessment of ADRs, Management of ADRs, Role of pharmacist in pharmacovigilance.

- A Textbook of Clinical Pharmacy Practice Essential concepts and skills –Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
- 2. Andrews EB, Moore N. Mann's Pharmacovigilance

- 3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A PathophysiologicApproach
- 4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it
- 5. Cohen MR. Medication Errors
- 6. Online:

http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Reduced.pdf http://curriculum.racgp.org.au/statements/quality-use-of-medicines/ http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf

7. Relevant review articles from recent medical and pharmaceutical literature.

CLINICAL TOXICOLOGY (Core Elective – II)

Course Objective: In the current scenario of accidental, homicidal and suicidal excessive consumption of drugs, pesticides, heavy metals and other poisonings, this elective helps the students to acquire the required knowledge and skills in the management of poisoning.

Course Outcome: At the end of the course the student is equipped with handling the first aid, elimination enhancement and treatment of poisoning and supportive care in poisoning due to

- Pesticides
- Drug over usage
- Heavy metals
- Radiation
- Snakes and anthropod bites
- Food poisoning

The student also gains knowledge in substance abuse and treatment of drug dependence.

UNIT I

General principles involved in the management of poisoning, antidotes and the clinical applications.

UNIT II

Supportive care in clinical toxicology. Gut decontamination, elimination enhancement and toxicokinetics.

UNIT III

Clinical symptoms and management of acute poisoning with the following agents -

- a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
- b) Opiates overdose.
- c) Antidepressants
- d) Barbiturates and benzodiazepines.
- e) Alcohol: ethanol, methanol.
- f) Paracetamol and salicylates.
- g) Non-steroidal anti-inflammatory drugs.
- h) Hydrocarbons: Petroleum products and PEG.
- i) Caustics: inorganic acids and alkalis.
- j) Radiation poisoning

UNIT IV

Clinical symptoms and management of chronic poisoning with the following agents -

- a) Heavy metals: Arsenic, lead, mercury, iron, copper
- b) Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.
- c) Plants poisoning. Mushrooms, Mycotoxins.
- d) Food poisonings
- e) Envenomations Arthropod bites and stings.

UNIT V

Substance abuse: Signs and symptoms of substance abuse and treatment of dependence

- a) CNS stimulants: amphetamine
- b) Opioids
- c) CNS depressants
- d) Hallucinogens: LSD
- e) Cannabis group

f) Tobacco

- 1. Matthew j ellenhorn. Ellenhorns medical toxicology diagnosis and treatment of poisoning. Second edition. Williams and willkins publication, london b.
- V V Pillay. Handbook of forensic medicine and toxicology. Thirteenth edition 2003 paras publication, Hyderabad

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD I Year - II Sem M. Pharm (HCP) ADVANCED DRUG DELIVERY SYSTEMS (Core Elective - II)

Course Objective: The students shall know the pharmacokinetic and pharmacodynamic on the basis of CDDS. They also know the design evaluation and application related to oral, parenteral, transdermal, implants, bioadhesives and targeted drug delivery systems.

Course Outcomes: Students will know the fabrication, design, evaluation and application of above drug delivery systems.

UNIT I

Fundamentals of controlled drug delivery systems, pharmacokinetic and pharmacodynamic basis of controlled drug delivery. Design, fabrication, evaluation and applications of the following controlled releasing systems

- a. Controlled release oral drug delivery systems
- b. Parenteral controlled release drug delivery systems

UNIT II

Design, fabrication, evaluation and applications of the following

- a) Implantable Therapeutic systems
- b) Transdermal delivery systems
- c) Ocular and Intrauterine delivery systems
- d) Vaccine delivery : Delivery systems used to promote uptake, absorption enhancers, oral immunization, controlled release microparticles form vaccine development

UNIT III

Biochemical and molecular biology approaches to controlled drug delivery of

- a. Bioadhesive drug delivery systems
- b. Nasal drug delivery systems
- c. Drug delivery to Colon

Biochemical and molecular biology approaches to control drug delivery of

- a. Liposomes
- b. Niosomes
- c. Microspheres
- d. Nanoparticles
- e. Resealed erythrocytes

UNIT V

Drug targeting to particular organs

- a. Delivery to lungs
- b. Delivery to the brain and problems involved
- c. Drug targeting in neoplasams

TEXT BOOKS:

- 1. Novel Drug Delivery System by Yie W. Chien.
- 2. Controlled Drug Delivery by Joseph R. Robinson and Vincent H. L. Lee.
- 3. Controlled and Novel Drug Delivery Systems by N. K. Jain.
- 4. Targeted and Controlled Drug Delivery (Novel carrier systems) by S. P. Vyas and Khar.
- 5. Modern Pharmaceutics by Gilbert S. Banker and Christopher T. Rhodes..
- Advances in Drug Delivery, Vol 1, 2, 3 by Y. Madhusudan Rao, A. V. Jithan
 Oral Drug Delivery Technology, 2nd ed, by Aukunuru Jithan

STABILITY OF DRUGS AND DOSAGE FORMS (Open Elective - II)

Course Objective: These topics are designed impart a specialized knowledge to preserve the properties of drugs and dosage forms during manufacture storage and shelf life. The understanding of properties and evaluation of stability during storage, by solution and solid state against several factors of degradation

Course Outcome: The students will learn the evaluation of stability of solutions, solids and formulations against adverse conditions. The students should be able to suggest the measures to retain stability and storage conditions for retaining the efficacy of the products.

UNIT - I

Drug decomposition mechanisms:

- 1. Hydrolysis and acyltransfers: Nature of reaction, structure and utility, stabilization of Pharmaceutical examples.
- Oxidation: Nature of oxidation, kinetics of oxidation, oxidation pathways of pharmaceutical, Interest Inhibition of oxidation
- 3. Photolysis: Energetics of photolysis, kinetics photolysis, photolytic reactions of pharmaceutical interest, prevention of photolytic reactions.

UNIT - II

Solid state chemical decomposition: Kinetic of solids state decomposition, Pharmaceutical examples of solid state decomposition, Pure drugs, drug excipient and drug-drug interaction in solid state, methods of stabilization.

Physical stability testing of dosage forms:

- 1. Solids tablets, capsules, powder and granules
- 2. Disperse systems
- 3. Microbial decomposition
- 4. Over-view, physical stability of novel drug carriers, liposomes, niosomes, nano-particles.

UNIT - III

Identification and quantitative determination of preservatives, Antioxidants, colouring materials, emulsifiers and stabilizers in Pharmaceutical formulation.

Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration. Factors affecting extraction of drugs.

UNIT-IV

General method of analysis to determine the quality of raw materials used in cosmetic industry. .. Indian Standard Specifications (ISI) laid down for sampling and testing of various cosmetics in finished form by the Bureau of Indian Standards.

UNIT-V

Methods of analysis to determine the quality of cosmetics in the finished forms such as Hair care products, Skin care products, Baby care products, Dental products, Personal hygiene products, Colour cosmetics, Ethnic products, Colour makeup preparation, Lipsticks, Hair setting lotions and Eye shadows. Toxicity testing in cosmetics and Safety and Legislation of Cosmetic products. Stability studies: Concept of stability studies.

- a) cGMP& ICH guidelines for Accelerated stability Testing.
- b) Interaction of containers & closure Compatibility Testing.

REFERENCE BOOKS:

- 1. Comprehensive Pharmacy Review 5th Edition by Leon Shargel, Alan H. Mutnick, Paul F. Souney, Larry N. Sawnson 2004.
- 2. H. Beckett and J. B. Stenlake Practical Pharmaceutical Chemistry, Part I and Part II, 4th Edition. 3. G. H. Jeffery, J. Basset, J. Mendham, R. C. Denny (Rev. by) Vogels Text Book of Quantitative Chemical Analysis, 5th Edition 1989, ELBS.
- 3. The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia, Vol. I and Vol. II 2010.
- 4. J. B. Wilkinson and R. J. Moore: Herry's Cosmeticology; Longman Scientific and Technical Publishers, Singapore.
- 5. P. D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition 1997.
- 6. Classification of cosmetics raw materials and adjuncts IS 3958 of Indian Standards Institution (BIS).
- 7. Cosmetic and toilet goods methods of sampling IS 3958 of Indian Standards Institution (BIS).
- 8. Methods of sampling and test for various cosmetics as laid down by Bureau of Indian Standards.
- 9. Drug stability: Principles and practices by Jens T. Carstensen
- 10. Stability Testing of Drug Products by W. Grimm. 12. Stability of Drugs and Dosage Forms by Yoshioka and Stella.

PRINCIPLES OF DRUG DISCOVERY (Open Elective - II)

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

Outcome: 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

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

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

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

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

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

- Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007 Humana Press Inc.
- 2. Darryl León. Scott Markelln. 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.

BIOSTATISTICS AND RESEARCH METHODOLOGY (Open Elective – II)

Course Objective: The student shall know the introduction, scope of biostatistics and Research work, calculation and present of the data. It also informs the students, how the present research work writing and correlating.

Course Outcome: The student will be known the Biostatistics arrangement, presentation and formation of tables and charts. They also know the correlation and regression & application of different methods, analysis of data and also learn how to write dissertation, thesis and Research paper.

UNIT I

Introduction and scope of biostatistics: Use of statistics in Pharmacy. Population and Sample collection. Stages of research, types of data and methods of data collections. Data arrangement and presentation, formation of table and charts.

UNIT II

Measures of central tendency: computation of means, median and mode from grouped and ungrouped data.

Measure of dispersion: computation of variance, standard deviation, standard error and their coefficients.

UNIT III

Measures of Correlation and Regression: Experimental designing, planning of an experiment, replication and randomization. Probit analysis.

Probability rules: Binomial, Poison and Normal distribution.

Hypothesis testing: Student't' test, Chi square test, Analysis of Variance (ANOVA): 1-way, 2-way, 3-ways

UNIT IV

Developing a research question, Resources for research question,

Literature Review: Traditional Qualitative Review,

Meta-Analysis—A Quantitative Review

Preparation of Research Proposal

Variables—Definition of Variable, Types of variables (Dependent and Independent variables, Confounded variables), Measurement of variables, Types of measurement scales and their comparison. Reliability and Validity of Measurements.

UNIT V

The research report paper writing/ thesis writing

Different parts of the research paper

- 1. Title-Title of project with authors' name
- 2. Abstract Statement of the problem, Background list in brief and purpose and scope
- 3. Key words
- 4. Methodology- subject, apparatus, instrumentation and procedure
- 5. Results tables, graphs figure and statistical presentation
- 6. Discussion support or non-support of hypothesis, practical and theoretical implications
- 7. Conclusion
- 8. Acknowledgements
- 9. References
- 10. Errata

- 11. Importance of Spell check for entire projects
- 12. Uses of footnotes

TEXT BOOKS:

- 1. Deepak Chawla Neena Sondhi, Research Methodology Concepts and Cases, Vikas books
- Donald H. McBurney -Theresa L. White "Research Methods" (Cengage learning India Pvt.

REFERENCE BOOKS:

- 1. Remington's Pharmaceutical Sciences
- Theory & Practice of Industrial Pharmacy by Lachman
 Statistics for business and economics 3rd edition by Vikas books publications
- 4. Biostatistics & Computer applications by GN Rao and NK Tiwari
- 5. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
- 6. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
- 7. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.
- 8. Biostatistics and Computer Applications by G.N. Rao and N.K. Tiwari
- 9. Fundamentals of Biostatistics by Khan and Khanum
- 10. Research Methodology by RK Khanna bis and Suvasis Saha
- 11. Research methods and Quantity methods by G.N.Rao
- 12. A practical approach to PG dissertation.

SCREENING METHODS IN PHARMACOLOGY (Open Elective - II)

Course Objective: The students are going to study about various techniques for screening of drugs for various pharmacological activities and guide lines for handling animals and human and animal ethics for screening of drugs.

Course Outcome: The expected outcomes are students will know how to handle animals and know about various techniques for screening of drugs for different pharmacological activities, guidelines and regulations for screening new drug molecules on animals.

UNIT I

Care Handling and breeding techniques of laboratory animals, Regulations for laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.

UNIT II

Bioassays: Basic principles of Biological standardization: Methods used in the bio-assay of Rabbis Vaccine, Oxytocin, Tetanus Antitoxin and Diphtheria Vaccine. Test for pyrogens.

UNIT III

Toxicity tests: OECD guidelines, determination of LD50, acute, sub-acute and chronic toxicity studies.

UNIT IV

Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of cardiac and anti-diabetic activities.

UNIT V

Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of psychopharmacological, anti-inflammatory and analgesic activities.

TEXT BOOKS:

- 1. Screening methods in Pharmacology, Vol.-1&2 by Robert .A. Turner and Peter Hebborn.
- 2. Drug discovery and evaluation by H. G. Vogel and W. H. Vogel, Springerverlag, Berlin Heideleberg.
- 3. Handbook of experimental pharmacology by S. K. Kulkarni, Vallabh Prakashan, Delhi.

REFERENCE BOOKS:

- 1. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized tripartite guidelines Guidelines for good clinical practice, E6, May 1996.
- Good clinical practice Guidelines for Clinical trials on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001.

ENTREPRENEURSHIP MANAGEMENT (Open Elective - II)

Course Objective: This course is designed to impart knowledge and skills necessary to train the Students on entrepreneurship management.

Course Outcome: On completion of this course it is expected that students will be able to understand.

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies And Networking

UNIT I

Conceptual Frame Work: Concept need and process in entrepreneurship development. Role of enterprise in national and global economy. Types of enterprise – Merits and Demerits. Government policies and schemes for enterprise development. Institutional support in enterprise development and management.

UNIT II

Entrepreneur: Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role.

UNIT III

Launching And Organising An Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilisation -finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.

UNIT IV

Growth Strategies And Networking: Performance appraisal and assessment. Profitability and control measures, demands and challenges. Need for diversification. Future Growth – Techniques of expansion and diversification, vision strategies. Concept and dynamics. Methods, Joint venture, coordination and feasibility study.

UNIT V

Preparing Project Proposal to Start on New Enterprise Project work – Feasibility report; Planning, resource mobilization and implementation.

TEXT AND REFERENCE BOOKS:

- 1. Akhauri, M. M. P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
- 2. Hisrich, R. D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health & Co., Toronto.
- 3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship Starting Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
- 4. Meredith, G. G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
- 5. Patel, V.C. (1987): Women Entrepreneurship Developing New Entrepreneurs, Ahmedabad
- Arya kumar. (2012): Entrepreneurship- Creating and Leading an Entrepreneurial Organization, Pearson

PHARMACOTHERAPEUTICS - II LAB

The students are required to be posted to various clinical wards for their exposure with therapeutic management and other clinical aspects. They are expected to have experience and do a tutorial as well as case presentation in the following clinical conditions. The students have to make at least 10 case presentations covering most common diseases found in the hospital to which the college is attached. The student should also submit a record of the cases presented. The list of clinical cases presented should include follow-up of the clinical cases mentioned below from the day of admission till discharge and presented in the SOAP (Subjective, Objective, Assessment and Plan) format.

- I. The cases may be selected from the following diseases:
 - 1. Neurology& Psychiatry
 - 2. Oncology
 - 3. Infectious Diseases & Immunology
 - 4. Dermatology
- II. Rational use of medicines in special population admitted in above wards (three)
- III. Calculation of Bioavailability and Bioequivalence from the given data (two)
- IV. Interpretation of Therapeutic Drug Monitoring reports of a given patient of any of the above wards (three)
- V. Calculation of various Pharmacoeconomic outcome analysis for the given data from the above (two)

ASSIGNMENTS:

The students are required to submit a minimum of three written assignments (1500 to 2000 words) selected from the topics on different disease conditions given to them. The students are required to discuss both the clinical and therapeutic aspects in the same.

CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING LAB

List of Experiments:

- 1. Causality assessment of adverse drug reactions (three)
- 2. Detection and management of medication errors (three)
- 3. Manufacture of parenteral formulations, powders.
- 4. Drug information queries.
- 5. Inventory control
- 6. Study of Design and Management of Hospital pharmacy department of a hospital.
- 7. Composition of Pharmacy and Therapeutics committee Organization, functions, and limitations.
- 8. Development of a hospital formulary for a teaching hospital
- Various sources of drug information and systematic approach to provide unbiased drug information.
- Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.