JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

M. Pharmacy (PHARMACOLOGY)

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

I Year – I Semester

Category	Course Title	Int.	Ext.	L	Ρ	С
		marks	marks			
Core Course I	Advanced Pharmacology – I	25	75	4		4
Core Course II	Clinical Pharmacology and	25	75	4		4
	Pharmacotherapeutics					
Core Course III	Pharmacokinetics And Drug Metabolism	25	75	4		4
Core Elective I	1. Modern Pharmaceutical Analytical	25	75	4		4
	Techniques					
	2. Clinical Research and Pharmacovigilance					
Open Elective I	1. Pharmacoepidemiology and	25	75	4		4
	Pharmacoeconomics					
	2. Drug Regulatory Affairs					
	3. Herbal Cosmetics Technology					
	4. Pharmaceutical Management					
	5. Pharmaceutical Formulation Technology					
Laboratory I	Advanced Pharmacology- I Lab	25	75		6	3
Laboratory II	Clinical Pharmacology and	25	75		6	3
	Pharmacotherapeutics Lab					
Seminar I	Seminar	50			4	2
	Total Credits			20	16	28

I Year – II Semester

Category	Course Title	Int.	Ext.	L	Ρ	С
		marks	marks			
Core Course IV	Advanced Pharmacology- II	25	75	4		4
Core Course V	Pharmacological and Toxicological Screening	25	75	4		4
	Methods					
Core Course VI	Principles of Drug Discovery	25	75	4		4
Core Elective II	1. Quality Use of Medicines	25	75	4		4
	2. Principles of Toxicology					
Open Elective II	1. Stability of Drugs and Dosage Forms	25	75	4		4
	2. Biostatistics and Research Methodology					
	3. Entrepreneurship Management					
	4. Clinical Toxicology					
	5. Advanced Drug Delivery Systems					
Laboratory III	Advanced Pharmacology –II Lab	25	75		6	3
Laboratory IV	Advanced Screening Methods and Toxicology	25	75		6	3
	Lab					
Seminar II	Seminar	50			4	2
Total Credits				20	16	28

II Year - I Semester

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

II Year - II Semester

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

ADVANCED PHARMACOLOGY - II (Core Course - IV)

Course Objective: 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 Outcome: Upon completion of the course the student shall be able to:

- Explain the mechanism of drug actions at cellular and molecular level
- Discuss the Pathophysiology and pharmacotherapy of certain diseases
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment
 of diseases

UNIT I

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

Chemotherapy: Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as ß-lactams, aminoglycosides, quinolones, Macrolideantibiotics. Antifungal, antiviral, and anti-TB drugs.

UNIT III

Chemotherapy: Drugs used in Protozoal Infections Drugs used in the treatment of Helminthiasis Chemotherapy of cancer Immunopharmacology Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma and COPD. Immunosuppressants and Immunostimulants

UNIT IV

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

UNIT V

Free radicals Pharmacology: Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer. Protective activity of certain important antioxidant Recent Advances in Treatment: Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus

- 1. The Pharmacological basis of therapeutics- Goodman and Gill man's
- 2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy byDavid E Golan et al.
- 3. Basic and Clinical Pharmacology by B. G -Katzung
- 4. Pharmacology by H.P. Rang and M.M. Dale.
- 5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
- 6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
- 7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B. C. Yu.

- 8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists
- 9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (Robbins Pathology)
- 10. A Complete Textbook of Medical Pharmacology by Dr. S. K Srivastava published by A P C Avichal Publishing Company.
- K D. Tripathi. Essentials of Medical Pharmacology
 Principles of Pharmacology. The Pathophysiologic basis of drug Therapyby David E Golan, Armen H, Tashjian Jr., EhrinJ, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS (Core Course - V)

Course Objective: 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 Outcome: 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

Laboratory Animals: Common laboratory animals: Description, handling and applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications Anesthesia and euthanasia of experimental animals. Maintenance and breeding of laboratory animals. CPCSEA guidelines to conduct experiments on animals Good laboratory practice. Bioassay-Principle, scope and limitations and methods

UNIT II

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

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 and anti allergics. Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic, antidiarrheal and laxatives.

UNIT IV

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents. Anti cancer agents. Hepatoprotective screening methods.

UNIT V

Preclinical screening of new substances for the pharmacological activity using in vivo, in vitro, and other possible animal alternative models. Immunomodulators, Immunosuppressants and immunostimulants General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenousimmunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin. Limitations of animal experimentation and alternate animal experiments. Extrapolation of in vitro data to preclinical and preclinical to humans

- 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, S K. Kulkarni
- 11. Practical Pharmacology and Clinical Pharmacy, SK. Kulkarni, 3rd Edition.
- 12. David R. Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, 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 Bikash Medhi (Author), Ajay Prakash (Author)

PRINCIPLES OF DRUG DISCOVERY (Core Course - VI)

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

Course 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, sitespecific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design

REFERENCES

1. 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.

QUALITY USE OF MEDICINES (Core Elective - II)

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.

Course Outcome: 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 druguse, 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.

- 1. 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 Pathophysiologic Approach
- 4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it
- 5. Cohen MR. Medication Errors
- 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.

PRINCIPLES OF TOXICOLOGY (Core Elective - II)

Course Objective: 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 Outcome: 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

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

UNIT II

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

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

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, HERGassay.

Tier2- GI, renal and other studies

UNIT V

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

- 1. Hand book on GLP, Quality practices for regulated non-clinical research and development (<u>http://www.who.int/tdr/publications/documents/glphandbook</u>.pdf).
- 2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
- 3. Drugs from discovery to approval by Rick NG.
- 4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan
- 5. OECD test guidelines.
- 6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
- Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (<u>http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm</u> 073246.pdf)

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 should describe 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.
- 2. 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.
- 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.

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 publishers
- Donald H. McBurney Theresa L. White "Research Methods" (Cengage learning India Pvt. 2. Ltd)

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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD I Year – II Sem M. Pharm (Pharmacology) 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, co-ordination 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 EDII
- 6. Arya kumar.(2012): Entrepreneurship- Creating and Leading an Entrepreneurial Organization, Pearson

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD I Year – II Sem M. Pharm (Pharmacology) CLINICAL TOXICOLOGY (Open 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 (Pharmacology) ADVANCED DRUG DELIVERY SYSTEMS (Open 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

UNIT IV

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:

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

ADVANCED PHARMACOLOGY - II LAB

List of Experiments

1. To record the dose response curve of Histamine using isolated guinea-pig ileum preparation.

2. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum / rat fundus strip preparation.

3. To carry out bioassay of Histamine using isolated guinea-pig ileum preparation by interpolation method.

4. To carry out bioassay of Histamine using guinea-pig ileum preparation by three point method.

5. To carry out bioassay of Histamine using guinea-pig ileum preparation by four point method.

6. Effect of drugs on chick/rat mean arterial blood pressure (MABP) by using Condon's mercury manometer.

7. Effect of drugs on perfused frog heart

ADVANCED SCREENING METHODS & TOXICOLOGY LAB

List of Experiments

Study of theory, principle, procedure involved, and interpretation of given results for the following experiments:

- 1. Analgesic property of drug using analgesiometer.
- 2. Antiinflammatory effect of drugs using rat-paw edema method.
- 3. Anticonvulsant activity of drugs using maximal electroshock and pentylenetetrazole methods.

4. Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.

- 5. Locomotor activity evaluation of drugs using actophotometer and rotorod.
- 6. Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.
- 7. Antidiabetic activity using rats / mice.n
- 8. Hepatoprotective activity
- 9. Anti ulcer activity
- 10. Antioxidant activity
- 11. Toxicity studies as per OECD guidelines.
- 12. Functional observation battery tests (modified Irwin test)