JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Course Structure and Syllabi for M.Pharm-Pharmacology
(JNTUA-Affiliated Pharmacy Colleges 2017-18)

I YEAR - I Semester

S. No	Course Code	Subjects	L	T	P	C
1	17S01101	Modern Pharmaceutical Analytical Techniques	4	-	-	4
2	17S01102	Advanced Pharmacology-I	4	-	-	4
3	17S01103	Pharmacological and Toxicological Screening Methods-I	4	-	-	4
4	17S01104	Cellular and Molecular Pharmacology	4	-	-	4
5	**17S01105**	**Pharmaceutical Analysis Practical for Pharmacology**	**-**	**-**	**6**	**3**
6	17S01106	Pharmacology Practical I	-	-	6	3
7	17S01107	Seminar/Assignment	-	-	7	4
Total			16	-	19	26

I YEAR II Semester

S. No	Course Code	Subject	L	T	P	C
1	17S01201	Advanced Pharmacology II	4	-	-	4
2	17S01202	Pharmacological and Toxicological Screening Methods-II	4	-	-	4
3	17S01203	Principles of Drug Discovery	4	-	-	4
4	17S01204	Clinical Research and Pharmacovigilance	4	-	-	4
5	17S01205	Pharmacology Practical II	-	-	6	3
6	17S01206	Pharmacology Practical III	-	-	6	3
7	17S01207	Seminar/Assignment	-	-	7	4
Total			16	-	19	26

III SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S01301	Research Methodology and Biostatistics	4	-	-	4
2.	17S01302	Journal Club	1	-	-	1
3.	17S01303	Teaching Assignment	10	-	-	2
4.	17S01304	Comprehensive viva voce	-	-	-	2
5.	17S01305	Discussion / Presentation (Proposal presentation)	-	-	2	2
6.	17S01306	Research Work	-	-	28	14
Total			15	-	30	25

IV SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S01401	Journal Club	1	-	-	1
2.	17S01402	Research work	31	-	-	16
3.	17S01403	Discussion/ Final Presentation	3	-	-	3
Total			35	-	-	20

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S01101) MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know about,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY **60 HOURS**

1. 11 hrs

a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV Visible spectroscopy.

b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling,

Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors

affecting vibrationalfrequencies and Applications of IR spectroscopy

c. Spectroflourimetry: Theory of Fluorescence, Factorsaffecting fluorescence, Quenchers,

Instrumentation andApplications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorptionspectroscopy: Principle,

Instrumentation, Interferences andApplications.

2. 11hrs

NMR spectroscopy: Quantum numbers and their role in NMR,Principle, Instrumentation, Solvent requirement in NMR,Relaxation process, NMR signals in various compounds,Chemical shift, Factors influencing chemical shift, Spin-Spincoupling, Coupling constant, Nuclear magnetic double resonance,Brief outline of principles of FT-NMR and 13C NMR. Applicationsof NMR spectroscopy.

3. 11hrs

Mass Spectroscopy: Principle, Theory, Instrumentation of MassSpectroscopy, Different types of ionization like electron impact,chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers ofQuadrupole and Time of Flight, Mass fragmentation and its rules,Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

4. 11hrs

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: a)Paper chromatography b) Thin Layer chromatographyc) Ion exchange chromatography d) Column chromatographye) Gas chromatography f) High Performance Liquidchromatographyg) Affinity chromatography

5 11hrs

a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis

d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

b. X ray Crystallography: Production of X rays, Different X raydiffraction methods, Bragg's law, Rotating crystal technique, Xray powder technique, Types of crystals and applications of Xray diffraction.

c. Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.5hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein,Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler,Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4thedition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rdEdition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume11, Marcel Dekker Series

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S01102) ADVANCED PHARMACOLOGY - I

Scope

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, this subject helps the students to understand the concepts of drug action and mechanisms involved

Objectives

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 treatment of diseases

THEORY 60 Hrs

1. 12Hrs

General Pharmacology

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

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

2 12Hrs

Neurotransmission

a. General aspects and steps involved in neurotransmission.

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

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

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

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

Autonomic Pharmacology

Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

3 12Hrs

Central nervous system Pharmacology

General and local anesthetics, Sedatives and hypnotics, drugs used to treat anxiety.

Depression, psychosis, mania, epilepsy, neurodegenerativediseases.

Narcotic and non-narcotic analgesics.

4 12Hrs

Cardiovascular Pharmacology

Diuretics, antihypertensives, antiischemics, anti- arrhythmics,drugs for heart failure and hyperlipidemia.

Hematinics, coagulants , anticoagulants, fibrinolytics and antiplateletdrugs

5 12Hrs

Autocoid Pharmacology

The physiological and pathological role of Histamine, Serotonin,Kinins Prostaglandins Opioid autocoids.

Pharmacology of antihistamines, 5HT antagonists.

REFEERENCES

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-Lippincott Williams & 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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S01103) PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I

Scope

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

Objectives

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

THEORY 60 Hrs

1. 12Hrs

Laboratory Animals

Common laboratory animals: Description, handling and applications of different species and strains of animals.

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

Maintenance and breeding of laboratory animals.

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

Bioassay-Principle, scope and limitations and methods

2 12Hrs

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.

3 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.

4

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.

5 12Hrs

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

Iimmunomodulators, 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

Limitations of animal experimentation and alternate animal experiments.

Extrapolation of in vitro data to preclinical and preclinical to humans

REFERENCES

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 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 BikashMedhi (Author), Ajay Prakash (Author)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S01104) CELLULAR AND MOLECULAR PHARMACOLOGY

Scope:

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

Objectives:

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

- Explain the receptor signal transduction processes.
- Explain the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques as applicable forpharmacology

THEORY 60 Hrs

1. 12Hrs

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.

2 12Hrs

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.

3 12Hrs

Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA andwestern blotting, Recombinant DNA technology and gene therapy. Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinantDNA technology.

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

4 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

5 12Hrs

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 assays

Principles and applications of flow cytometry

b. Biosimilars

REFERENCES:

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 FrederickM.Ausuvel et al.

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M. Pharm – I year I Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S01105) PHARMACEUTICAL ANALYSIS PRACTICAL FOR PHARMACOLOGY

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis-spectrophotometer

2.Simultaneous estimation of multi component containing formulations by UV spectrophotometry

3. Experiments based on HPLC

4. Experiments based on Gas Chromatography

5. Estimation of riboflavin/quinine sulphate by fluorimetry

6. Estimation of sodium/potassium by flame photometry

7. Estimation of proteins by Braford/Lowry's in biological samples.

8. Estimation of RNA/DNA by UV Spectroscopy

9. Protein quantification Western Blotting.

10. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using soft wares

11. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)

12. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

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M. Pharm – I year I Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S01106) PHARMACOLOGY PRACTICAL - I

1. Handling of laboratory animals.

1. Various routes of drug administration.

2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.

3. Functional observation battery tests (modified Irwin test)

4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic,anticonvulsant activity.

5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic andmiotic activity.

6. Evaluation of diuretic activity.

7. Evaluation of antiulcer activity by pylorus ligation method.

8. Oral glucose tolerance test.

9. Isolation and identification of DNA from various sources (Bacteria,Cauliflower, onion, Goat liver).

10. Isolation of RNA from yeast

11. Gene amplification by PCR.

12. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).

13. Cell viability assays (MTT/Trypan blue/SRB).

14. DNA fragmentation assay by agarose gel electrophoresis.

15. DNA damage study by Comet assay.

16. Apoptosis determination by fluorescent imaging studies.

17. Enzyme inhibition and induction activity

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M. Pharm – I year II Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S01201) ADVANCED PHARMACOLOGY - II

Scope

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

Objectives

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

THEORY 60 Hrs

1. 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

2 12Hrs

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.

3 12Hrs

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

4 12Hrs

GIT Pharmacology

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

Chronopharmacology

Biological and circadian rhythms, applications of chronotherapy invarious diseases likecardiovascular disease, diabetes, asthma and peptic ulcer

5 12Hrs

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

REFERENCES

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 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-Lippincott Williams & Wilkins Publishers

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S01202) PHARMACOLOGICAL AND TOXICOLOGICAL SCREENINGMETHODS-II

Scope:

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

Objectives:

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

- Explain the various types of toxicity studies.
- Appreciate the importance of ethical and regulatory requirements for toxicity studies.
- Demonstrate the practical skills required to conduct the preclinical toxicity studies.

THEORY 60 Hrs

1. 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.

2 12Hrs

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

3 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

4 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 other studies

5 12Hrs

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

REFERENCES

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 of health 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 Conductof Human Clinical Trials and Marketing Authorization for Pharmaceuticals(http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S01203) PRINCIPLES OF DRUG DISCOVERY

Scope:

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

Objectives:

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

- Explain the various stages of drug discovery.
- Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
- Explain various targets for drug discovery.
- Explain various lead seeking method and lead optimization
- Appreciate the importance of the role of computer aided drug design in drug discovery

THEORY 60 Hrs

1. 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.

2 12Hrs

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

3 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,

4 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.

5 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.

REFERENCES

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular 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 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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S01204) CLINICAL RESEARCH AND PHARMACOVIGILANCE

Scope:

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

Objectives:

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

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

THEORY 60 Hrs

1. 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

2 12Hrs

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

3 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.

4 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

5 12Hrs

a. 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, safetypharmacology

REFERENCES

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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S01205) PHARMACOLOGICAL PRACTICAL - II

1. To record the DRC of agonist using suitable isolated tissues preparation.

2. To study the effects of antagonist/potentiating agents on DRC of agonistusing suitable isolated tissue preparation.

3. To determine to the strength of unknown sample by matching bioassay byusing suitable tissue preparation.

4. To determine to the strength of unknown sample by interpolation bioassayby using suitable tissue preparation

5. To determine to the strength of unknown sample by bracketing bioassayby using suitable tissue preparation

6. To determine to the strength of unknown sample by multiple pointbioassay by using suitable tissue preparation.

7. Estimation of PA2 values of various antagonists using suitable isolatedtissue preparations.

8. Drug absorption studies by averted rat ileum preparation.

9. ADR reporting

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M. Pharm – I year II Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S01206) PHARMACOLOGY PRACTICALS-III

1. To study the effects of various drugs on isolated heart preparations

2. Recording of rat BP, heart rate and ECG.

3.. Recording of rat ECG

4. Acute oral toxicity studies as per OECD guidelines.

5. Acute dermal toxicity studies as per OECD guidelines.

6. Repeated dose toxicity studies- Serum biochemical, haematological, urineanalysis, functional observation tests and histological studies.

7. Drug mutagenicity study using mice bone-marrow chromosomal aberrationtest.

8.. Protocol design for clinical trial.(3 Nos.)

9. Design of ADR monitoring protocol.

10. In-silico docking studies. (2 Nos.)

11. In-silico pharmacophore based screening.

12. In-silico QSAR studies.

REFERENCES

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh

2. Hand book of Experimental Pharmacology-S.K.Kulakarni

3. Text book of in-vitro practical Pharmacology by Ian Kitchen

4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbalchoudhary and William Thomsen

5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel andAndrew B.C.Yu.

6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and DrugMetabolism for Industrial Scientists.,

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – III Sem. (Pharmacology)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S01301) RESEARCH METHODOLOGY & BIOSTATISTICS

UNIT – I

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

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

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

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

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

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(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

SEMESTER – I

S. No.	Course code	Course Name	Hours per week			Credits
			L	T	P	
1.	21S01101	Modern Pharmaceutical Analytical Techniques	4	-	-	4
2.	21S01102	Advanced Pharmacology-I	4	-	-	4
3.	21S01103	Clinical Pharmacology and Pharmacotherapeutics	4	-	-	4
4.	21S01104	Cellular and Molecular Pharmacology	4	-	-	4
5.	21S01105	Modern Pharmaceutical Analytical Techniques Lab	-	-	6	3
6.	21S01106	Advanced Pharmacology – I Lab	-	-	6	3
7.	21DAC101a 21DAC101b 21DAC101c	**Audit Course – I** English for Research paper writing Disaster Management Sanskrit for Technical Knowledge	2	-	-	0
8.	21S01107	Seminar/Assignment	-	1	6	4
		Total	18	1	18	26

SEMESTER – II

S.No.	Course code	Course Name	Hours per			Credits
			L	T	P	
1.	21S01201	Advanced Pharmacology- II	4	-	-	4
2.	21S01202	Pharmacological Screening Methods & Toxicology	4	-	-	4
3.	21S01203	Principles of Drug Discovery	4	-	-	4
4.	21S01204	Clinical research and Pharmacovigilance	4	-	-	4
5.	21S01205	Advanced Pharmacology -II Lab	-	-	6	3
6.	21S01206	Pharmacological Screening Methods & Toxicology Lab	-	-	6	3
7.	21DAC201a 21DAC201b 21DAC201c	**Audit Course – II** Pedagogy Studies Stress Management from Yoga Personality Development through Life Enlightenment Skills	2	-	-	0
8.	21S01207	Seminar/Assignment	-	1	6	4
		Total	18	1	18	26

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
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ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

SEMSTER - III

S.No.	Course code	Course Name	Hours per			Credits
			L	T	P	
1.	21DRM101	Research Methodology and Intellectual Property Rights	4	-	-	4
2.	21SOE301a 21SOE301b 21SOE301c	**Open Elective** Pharmaceutical Validation Biostatistics Entrepreneurship Management	3	-	-	3
3.	21S01302	Teaching Practice/Assignment	-	-	4	2
4.	21S01303	Comprehensive viva voce	-	-	-	2
	21S01304	Research Work – I	-		24	12
		Total	7	-	32	23

SEMESTER - IV

S.No.	Course code	Course Name	Hours per			Credits
			L	T	P	
1.	21S01401	Co-Curricular Activities	2			2
2.	21S01402	Research Work – II	3		30	18
		Total	5		30	20

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(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

Course Code	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES	L	T	P	C
21S01101		4	0	0	4
	Semester	I			

Course Objectives:

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Course Outcomes (CO): Student will be able to

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

UNIT - I

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.

UNIT - II

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.

UNIT - III

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spincoupling, Coupling constant, Nuclear magnetic double resonance,Brief outline of principles of FT-NMR and ^{13}C NMR. Applications of NMR spectroscopy

UNIT - IV

Mass Spectroscopy: Principle, Theory, Instrumentation of MassSpectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

UNIT - V

Chromatography

Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation, Principle, instrumentation, selection of solvents; chromatographic parameters, factors affecting resolution, applications of the following:

a) Thin Layer chromatography; b) High Performance Thin Layer Chromatography
c) Paper Chromatography; d) Column chromatography
e) Gas chromatography; f) High Performance Liquid chromatography
g) Affinity chromatography; h) Gel Chromatography
i)Hyphenated techniques :

- Ultra High Performance Liquid chromatography- Mass spectroscopy
- Gas Chromatography-Mass Spectroscopy

Reference Books:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
3. Spectrometric Identification of Organic compounds - Robert M Silverstein,Sixth edition, John Wiley & Sons, 2004.
4. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler,Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

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(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

5. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
6. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4thedition, CBS Publishers, New Delhi, 1997.
7. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
8. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi,3rd Edition, CBS Publishers, New Delhi, 1997.
9. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol11, Marcel. Dekker Series
10. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley esternLtd., Delhi.
11. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley& Sons, 1982.
12. Organic Chemistry by I. L. Finar
13. Quantitative Analysis of Drugs by D. C. Garrett
14. HPTLC by P.D. Seth
15. Indian Pharmacopoeia 2007
16. High Performance thin layer chromatography for the analysis of medicinal plants by Eike
17. Reich, Anne Schibli
18. Introduction to instrumental analysis by Robert. D. Braun

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(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

Course Code	ADVANCED PHARMACOLOGY- I	L	T	P	C
21S01102		4	0	0	4
	Semester	I			

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, this subject helps the students to understand the concepts of drug action and mechanisms involved

Course Outcomes (CO): Student will 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 treatment of diseases

UNIT – I

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

Neurotransmission
a. General aspects and steps involved in neurotransmission.
b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetylcholine).
c.Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters histamine, serotonin, dopamine, GABA, glutamate and glycine].
d.Non-adrenergic non-cholinergic transmission (NANC). Co-transmission.
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
Autonomic Pharmacology: Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

UNIT - III

Central nervous system Pharmacology
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

Cardiovascular Pharmacology
Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia. Hematinics, coagulants, anticoagulants, fibrinolytics and antiplatelet drugs

UNIT - V

Autacoid Pharmacology
The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins Opioid autacoids. Pharmacology of antihistamines, 5HT antagonists

Reference Books:

1. The Pharmacological Basis of Therapeutics, Goodman and Gillman‘s
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan, Armen H, Tashjian Jr, EhrinJ, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott

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(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

Williams & 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 and Andrew B. C. Yu.
6. Graham Smith. Oxford textbook of Clinical Pharmacology.
7. Avery's Drug Treatment
8. Dipiro Pharmacology, Pathophysiological approach.
9. Green Pathophysiology for Pharmacists

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(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

Course Code	CLINICAL PHARMACOLOGY AND PHARMACOTHERAPEUTICS	L	T	P	C
21S01103		4	0	0	4
	Semester	**I**			

Course Objectives:

This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.

Course Outcomes (CO): Student will be able to

- The pathophysiology of selected disease states and the rationale for drug therapy; the controversies in drug therapy;
- The importance of preparation of individualized therapeutic plans based on diagnosis;
- Needs to 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 effects);
- Summarize the therapeutic approach to management of these diseases including reference
- To the latest available evidence;
- Therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).
- Pathophysiology and applied Pharmacotherapeutics of diseases associated with following system/diseases with of special reference to the drug of choice

UNIT - I

Principles of Pharmacokinetics
1. Revision of basic concepts.
2. Clinical Pharmacokinetics.
a. Dose – response in man
b. Influence of renal and hepatic disease on Pharmacokinetics
c. Therapeutics drug monitoring & individualization of drug therapy
d. Population Pharmacokinetics.

UNIT - II

Adverse Drug Reactions, Drug Interactions, ADR monitoring & Pharmacovigilance

UNIT - III

Pathophysiology and drug therapy of the following disorders. Schizophrenia, anxiety, depression, epilepsy, Parkinson's, alzheimer's diseases, migraine, hypertension, angina pectoris, arrhythmias, atherosclerosis, myocardial infarction.

UNIT - IV

Pathophysiology and drug therapy of the following disorders. TB, leprosy, leukemia, solid tumors, lymphomas, psoriasis, respiratory, urinary, G.I. tract infections, endocarditis, fungal and HIV infection, rheumatoid arthritis, glaucoma, menstrual disorders, menopause.

UNIT - V

Drug therapy in
a) Geriatrics
b) Paediatrics
c) Pregnancy & Lactation.
d) Renal & hepatic insufficiency

Reference Books:

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(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

1. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
2. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.
3. Pathologic basis of disease - Robins SL, W.B. Saunders publication.
4. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
5. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
6. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
7. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
8. Relevant review articles from recent medical and pharmaceutical literature.
9. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
10. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
11. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA

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ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

Course Code	CELLULAR AND MOLECULAR PHARMACOLOGY	L	T	P	C
21S01104		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): Student will be able to

- Explain the receptor signal transduction processes.
- Explain the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques as applicable for pharmacology

UNIT – I

Cell biology
Structure and functions of cell and its organelles Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing
Cell cycles and its regulation. Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy

UNIT – II

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

UNIT – III

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

UNIT – IV

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,

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

Immunotherapeutics in clinical practice		
UNIT – V		
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 assays Principles and applications of flow cytometry b. Biosimilars		
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 FrederickM.Ausuvel et al.		

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

Course Code	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES LAB	L	T	P	C
21S01105		0	0	6	3
	Semester	I			

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis Spectrophotometer.
2. Simultaneous estimation of multi component containing formulations by UV Spectrophotometry
3. Effect of pH and solvent on UV –Spectrum
4. Determination of Molar absorption coefficient
5. Estimation of riboflavin/ quinine sulphate by fluorimetry
6. Study of quenching effect by fluorimetry
7. Estimation of sodium or potassium by flame photometry
8. Colorimetric determination of drugs by using different reagents
9. Qunatitative determination of functional groups
10. Experiments based on Column chromatography
11. Experiments based on HPLC
12. Experiments based on Gas Chromatography

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

Course Code	ADVANDED PHARMACOLOGY – I LAB	L	T	P	C
21S01106		4	0	0	4
	Semester	I			

List of experiments

Handling of laboratory animals.

1. Various routes of drug administration.
2. Study of techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
4. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
5. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by four point method.
7. Estimation of pA2 value on isolated tissues
8. Bioassay of 5-HT using rat fundus strip
9. Bioassay of oxytocin using rat uterus

Reference Books:

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M. N. Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author) Jaypee brothers' medical publishers Pvt. Ltd

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

Course Code	ADVANCED PHARMACOLOGY – II	L	T	P	C
21S01201		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): Student will 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, Macrolide antibiotics. 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

Reference Books:

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

9. Robbins & Cortan Pathologic Basis of Disease, 9th Ed. (RobbinsPathology)
10. A Complete Textbook of Medical Pharmacology by Dr. S. K Srivastava published by A P C Avichal Publishing Company.
11 K D. Tripathi. Essentials of Medical Pharmacology Principles of Pharmacology.
12.The Pathophysiologic basis of drug Therapyby David E Golan, Armen H, Tashjian Jr., EhrinJ, Armstrong, April W, Armstrong, Wolters, Kluwer-Lippincott Williams & Wilkins Publishers

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ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

Course Code	PHARMACOLOGICAL SCREENING METHODS & TOXICOLOGY	L	T	P	C
21S01202		4	0	0	4
	Semester	II			

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): Student will 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, anti-inflammatory 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, antiarrhythmics, 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 homogenous immunoassay 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

Reference Books:

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(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

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, S K. 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)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

Course Code	PRINCIPLES OF DRUG DISCOVERY	L	T	P	C
21S01203		4	0	0	4
	Semester	1I			

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 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. Denovo 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.

Reference Books:

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 MarkelIn. Silico Technologies in Drug Target Identification and Validation 2006 by Taylor and Francis Group, LLC.

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(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

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 inMedicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design.
6. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
7. Abby L .Parrill. M. Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
8. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

Course Code	CLINICAL RESEARCH AND PHARMACOVIGILANCE	L	T	P	C
21S01204		4	0	0	4
	Semester	**I1**			

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): Student will be able to

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in pharmacovigilance

UNIT - I		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		12Hrs

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

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(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

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.
Reference Books:
1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001. 2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6; May 1996.230 3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi. 4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons. 5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications. 6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone. 7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes. 8. Textbook of Pharmacovigilance: Concept and Practice. G. P. Mohanta and P. K. Manna. 2016, Pharma Med Press. 9. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press

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ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

Course Code	ADVANDED PHARMACOLOGY – II LAB	L	T	P	C
21S01205		0	0	6	3
	Semester	1I			

1. Effect of drugs on chick/rat mean arterial blood pressure (MABP) by using Condon's mercury manometer.
2. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
3. Isolation of RNA from yeast
4. Gene amplification by PCR.
5. Enzyme based in-vitro assays (MPO, AChEs, α amylase, α glucosidase).
6. Cell viability assays (MTT/Trypan blue/SRB).
7. DNA fragmentation assay by agarose gel electrophoresis.
8. DNA damage study by Comet assay.
9. Apoptosis determination by fluorescent imaging studies.
10. Enzyme inhibition and induction activity

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(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

Course Code	PHARMACOLOGICAL SCREENING METHODS AND TOXICOLOGY LAB		L	T	P	C
21S01206			0	0	6	3
Pre-requisite		Semester	I1			

1. Analgesic property of drug using analgesiometer.
2. Anti-inflammatory 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 rotarod.
6. Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.
7. Antidiabetic activity using rats / mice
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)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

Course Code	RESEARCH METHODOLOGY AND	L	T	P	C
21DRM101	INTELLECTUAL PROPERTY RIGHTS	4	0	0	4
	Semester	III			

Course Objectives:

- 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 to be 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

Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem. Approaches of investigation of solutions for research problem, data collection, analysis, interpretation, Necessary instrumentations

UNIT - II

Effective literature studies approaches, analysis, Plagiarism, Research ethics

UNIT - III

Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

UNIT - IV

Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

UNIT - V

Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs

Textbooks:

1. Stuart Melville and Wayne Goddard, "Research methodology: an introduction for science & engineering students'"
2. Wayne Goddard and Stuart Melville, "Research Methodology: An Introduction"

Reference Books:

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(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

1. Ranjit Kumar, 2nd Edition, "Research Methodology: A Step by Step Guide for beginners"
2. Halbert, "Resisting Intellectual Property", Taylor & Francis Ltd ,2007.
3. Mayall, "Industrial Design", McGraw Hill, 1992.
4. Niebel, "Product Design", McGraw Hill, 1974.
5. Asimov, "Introduction to Design", Prentice Hall, 1962.
6. Robert P. Merges, Peter S. Menell, Mark A. Lemley, "Intellectual Property in New Technological Age", 2016.
8. T. Ramappa, "Intellectual Property Rights Under WTO", S. Chand, 2008

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ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

AUDIT COURSE-I

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

Course Code	ENGLISH FOR RESEARCH PAPER WRITING	L	T	P	C
21DAC101a		2	0	0	0
	Semester	I			

Course Objectives: This course will enable students:

- Understand the essentials of writing skills and their level of readability
- Learn about what to write in each section
- Ensure qualitative presentation with linguistic accuracy

Course Outcomes (CO): Student will be able to

- Understand the significance of writing skills and the level of readability
- Analyze and write title, abstract, different sections in research paper
- Develop the skills needed while writing a research paper

UNIT - I		Lecture Hrs:10

1Overview of a Research Paper- Planning and Preparation- Word Order- Useful Phrases - Breaking up Long Sentences-Structuring Paragraphs and Sentences-Being Concise and Removing Redundancy -Avoiding Ambiguity

UNIT - II		Lecture Hrs:10

Essential Components of a Research Paper- Abstracts- Building Hypothesis-Research Problem - Highlight Findings- Hedging and Criticizing, Paraphrasing and Plagiarism, Cauterization

UNIT - III		Lecture Hrs:10

Introducing Review of the Literature – Methodology - Analysis of the Data-Findings - Discussion-Conclusions-Recommendations.

UNIT - IV		Lecture Hrs:9

Key skills needed for writing a Title, Abstract, and Introduction

UNIT - V		Lecture Hrs:9

Appropriate language to formulate Methodology, incorporate Results, put forth Arguments and draw Conclusions

Suggested Reading

1. Goldbort R (2006) Writing for Science, Yale University Press (available on Google Books) Model Curriculum of Engineering & Technology PG Courses [Volume-I]
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman'sbook
4. Adrian Wallwork , English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011

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(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

Course Code	DISASTER MANAGEMENT	L	T	P	C
21DAC101b		2	0	0	0
	Semester	**I**			

Course Objectives: This course will enable students:

- Learn to demonstrate critical understanding of key concepts in disaster risk reduction and humanitarian response.
- Critically evaluatedisasterriskreduction and humanitarian response policy and practice from Multiple perspectives.
- Developanunderstandingofstandardsofhumanitarianresponseandpracticalrelevanceinspecific types of disasters and conflict situations
- Criticallyunderstandthestrengthsandweaknessesofdisastermanagementapproaches,planningand programming in different countries, particularly their home country or the countries they work in

UNIT - I

Introduction:
Disaster:Definition,FactorsandSignificance;DifferenceBetweenHazardandDisaster;Naturaland Manmade Disasters: Difference, Nature, Types and Magnitude.

Disaster Prone Areas in India:
Study of Seismic Zones; Areas Prone to Floods and Droughts, Landslides and Avalanches; Areas Prone to Cyclonic and Coastal Hazards with Special Reference to Tsunami; Post- Disaster Diseases and Epidemics

UNIT - II

Repercussions of Disasters and Hazards:
Economic Damage, Loss of Human and Animal Life, Destruction of Ecosystem. Natural Disasters: Earthquakes,Volcanisms,Cyclones,Tsunamis,Floods,DroughtsandFamines,Landslides and Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks and Spills, Outbreaks of Disease and Epidemics, War and Conflicts.

UNIT - III

Disaster Preparedness and Management:
Preparedness: Monitoring of Phenomena Triggering ADisasteror Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological and Other Agencies, Media Reports: Governmental and Community Preparedness.

UNIT - IV

Risk Assessment Disaster Risk:
Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. TechniquesofRiskAssessment,GlobalCo-OperationinRiskAssessmentand Warning, People's Participation in Risk Assessment. Strategies for Survival.

UNIT - V

Disaster Mitigation:
Meaning,ConceptandStrategiesofDisasterMitigation,EmergingTrendsInMitigation.Structural Mitigationand Non-Structural Mitigation, Programs of Disaster Mitigation in India.

Suggested Reading

1. R.Nishith,SinghAK,"DisasterManagementinIndia:Perspectives,issuesandstrategies
2. "'New Royal book

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(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

Company..Sahni,PardeepEt.Al.(Eds.),"DisasterMitigationExperiencesAndReflections",PrenticeHall OfIndia, New Delhi.
3. GoelS.L.,DisasterAdministrationAndManagementTextAndCaseStudies",Deep&Deep Publication Pvt. Ltd., New Delhi

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(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

Course Code	SANSKRITFOR TECHNICAL KNOWLEDGE	L	T	P	C
21DAC101c		2	0	0	0
	Semester	**I**			

Course Objectives: This course will enable students:

- To get a working knowledge in illustrious Sanskrit, the scientific language in the world
- Learning of Sanskrit to improve brain functioning
- LearningofSanskrittodevelopthelogicinmathematics,science&othersubjects enhancing the memory power
- The engineering scholars equipped with Sanskrit will be able to explore the huge
- Knowledge from ancientliterature

Course Outcomes (CO): Student will be able to

- Understanding basic Sanskrit language
- Ancient Sanskrit literature about science &technology can be understood
- Being a logical language will help to develop logic in students

UNIT - I

Alphabets in Sanskrit,

UNIT - II

Past/Present/Future Tense, Simple Sentences

UNIT - III

Order, Introduction of roots

UNIT - IV

Technical information about Sanskrit Literature

UNIT - V

Technical concepts of Engineering-Electrical, Mechanical, Architecture, Mathematics

Suggested Reading

1.“Abhyaspustakam” –Dr.Vishwas, Sanskrit-Bharti Publication, New Delhi
2.“Teach Yourself Sanskrit” Prathama Deeksha- VempatiKutumbshastri, RashtriyaSanskrit Sansthanam, New Delhi Publication
3.“India’s Glorious ScientificTradition” Suresh Soni, Ocean books (P) Ltd.,New Delhi

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

AUDIT COURSE-II

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
(Established by Govt. of A.P., ACT No.30 of 2008)
ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

Course Code	PEDAGOGY STUDIES	L	T	P	C
21DAC201a		2	0	0	0
	Semester	II			

Course Objectives: This course will enable students:

- Reviewexistingevidenceonthereviewtopictoinformprogrammedesignandpolicy making undertaken by the DfID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

Course Outcomes (CO): Student will be able to

Students will be able to understand:

- Whatpedagogicalpracticesarebeingusedbyteachersinformalandinformalclassrooms in developing countries?
- What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
- Howcanteachereducation(curriculumandpracticum)andtheschoolcurriculumand guidance materials best support effective pedagogy?

UNIT - I

Introduction and Methodology: Aims and rationale, Policy back ground, Conceptual frame work and terminology Theories oflearning,Curriculum,Teachereducation.Conceptualframework,Research questions**.** Overview of methodology and Searching.

UNIT - II

Thematic overview: Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

UNIT - III

Evidence on theeffectivenessofpedagogicalpractices,Methodologyfortheindepthstage:quality assessmen t of included studies. How can teacher education (curriculumandpracticum) andthescho curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of th body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers' attitudes and beliefs and Pedagogic strategies.

UNIT - IV

Professional development: alignment with classroom practices and follow-up support, Peer support, Support from the head teacherandthecommunity.Curriculumandassessment,Barrierstolearning:limitedresourcesand large class sizes

UNIT - V

Researchgapsandfuturedirections: Researchdesign**,**Contexts**,**Pedagogy**,**Teachereducation**,** Curriculum and assessment**,** Dissemination and research impact.

Suggested Reading

1. AckersJ,HardmanF(2001)ClassroominteractioninKenyanprimaryschools,Compare, 31 (2): 245-261.
2. AgrawalM(2004)Curricularreforminschools:Theimportanceofevaluation,Journalof
3. Curriculum Studies, 36 (3): 361-379.

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M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

4. AkyeampongK(2003) Teacher training in Ghana - does it count? Multi-site teachereducation research project (MUSTER) country report 1. London: DFID.
5. Akyeampong K, LussierK, PryorJ, Westbrook J (2013)Improving teaching and learning of basic maths and reading in Africa: Does teacherpreparation count?International Journal Educational Development, 33 (3): 272–282.
6. Alexander RJ(2001) Culture and pedagogy: International comparisons in primary education. Oxford and Boston: Blackwell.
   Chavan M (2003)ReadIndia: A mass scale, rapid, 'learning to read'campaign.
7. www.pratham.org/images/resource%20working%20paper%202.pdf.

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M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

Course Code	STRESSMANAGEMENT BY YOGA	L	T	P	C
21DAC201b		2	0	0	0
	Semester	**II**			

Course Objectives: This course will enable students:

- To achieve overall health of body and mind
- To overcome stres

Course Outcomes (CO): Student will be able to

- Develop healthy mind in a healthy body thus improving social health also
- Improve efficiency

UNIT - I

Definitions of Eight parts of yog.(Ashtanga)

UNIT - II

Yam and Niyam.

UNIT - III

Do`sand Don't'sin life.
i) Ahinsa,satya,astheya,bramhacharyaand aparigrahaii)
Shaucha,santosh,tapa,swadhyay,ishwarpranidhan

UNIT - IV

Asan and Pranayam

UNIT - V

i)Variousyogposesand theirbenefitsformind &body
ii)Regularizationofbreathingtechniques and its effects-Types ofpranayam

Suggested Reading

1.'Yogic Asanas forGroupTarining-Part-I": Janardan SwamiYogabhyasiMandal, Nagpur
2."Rajayogaor conquering the Internal Nature" by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata

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ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

Course Code	PERSONALITY DEVELOPMENT THROUGHLIFE ENLIGHTENMENTSKILLS	L	T	P	C
21DAC201c		2	0	0	0
	Semester	**II**			

Course Objectives: This course will enable students:

- To learn to achieve the highest goal happily
- To become a person with stable mind, pleasing personality and determination
- To awaken wisdom in students

Course Outcomes (CO): Student will be able to

- StudyofShrimad-Bhagwad-Geetawillhelpthestudentindevelopinghispersonalityand achieve the highest goal in life
- The person who has studied Geetawilllead the nation and mankind to peace and prosperity
- Study of Neetishatakam will help in developing versatile personality of students

UNIT - I

Neetisatakam- Holistic development of personality
Verses-19,20,21,22(wisdom)
Verses-29,31,32(pride &heroism)
Verses-26,28,63,65(virtue)

UNIT - II

Neetisatakam- Holistic development of personality
Verses-52,53,59(dont's)
Verses-71,73,75,78(do's)

UNIT - III

Approach to day to day work and duties.
ShrimadBhagwadGeeta:Chapter2-Verses41,47,48,
Chapter3-Verses13,21,27,35,Chapter6-Verses5,13,17,23,35,
Chapter18-Verses45,46,48.

UNIT - IV

Statements of basic knowledge.
ShrimadBhagwadGeeta:Chapter2-Verses 56,62,68
Chapter12 -Verses13,14,15,16,17,18
Personality of Rolemodel. Shrimad Bhagwad Geeta:

UNIT - V

Chapter2-Verses 17,Chapter3-Verses36,37,42,
Chapter4-Verses18,38,39
Chapter18– Verses37,38,63

Suggested Reading

1."SrimadBhagavadGita"bySwamiSwarupanandaAdvaitaAshram(PublicationDepartment), Kolkata
2.Bhartrihari'sThree Satakam (Niti-sringar-vairagya) by P.Gopinath, RashtriyaSanskrit Sansthanam, New Delhi.

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ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

OPEN ELECTIVE

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ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

Course Code	PHARMACEUTICAL VALIDATION	L	T	P	C
21SOE301a	(Elective)	3	0	0	3
	Semester	III			

Course Objectives:

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application

Course Outcomes (CO): Student will be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

UNIT - I

Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan. Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status -Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipment, Qualification of Analytical Instruments and Laboratory equipments

UNIT - II

Qualification of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer,
FTIR, GC, HPLC, HPTLC
Qualification of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT - III

Qualification of laboratory equipments: Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus.
Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.

UNIT - IV

Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment. Cleaning of Facilities. Cleaning in place (CIP).

UNIT - V

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP.

Textbooks:

1. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol.129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman,Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.

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ANANTHAPURAMU – 515 002 (A.P) INDIA

M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE& SYLLABI

Course Code	BIOSTATISTICS	L	T	P	C
21SOE301b	(Elective)	3	0	0	3
	Semester	III			

Course Objectives:

The student shall know the introduction, scope of biostatistics and Research work, calculation and present of the data

Course Outcomes (CO): Student will be able to

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

UNIT - I

An introduction to statistics and biostatistics-collection and organization of data, graphical, pictorial presentation of data, measures of central tendency and dispersion, sampling techniques, sample size, Coefficient of variation, mean error, relative error, precision and accuracy

UNIT - II

Tests of significance: Testing hypotheses – Principles and applications of Z, t, F–ratio and chi-square tests in pharmaceutical and medical research. Non-parametric tests: sign test, Wilcoxon signed rank test, Wilcoxon rank sum test, Kruskal Wallis test, run test and median tests.

UNIT - III

Design of Experiments: Principles of randomization, replication and local control; CRD, RBD, LSD – their applications and analysis of data;

UNIT - IV

Factorial Experiments – Principles and applications; Probit analysis: Dose – effect relationships, calculation of LD50, ED50

UNIT - V

Statistical quality control: Meaning and uses, Construction of X, R, P, ηp and charts.

Textbooks:

1. Statistics for business and economics 3rd edition by Vikas books publications
2. Biostatistics & Computer applications by GN Rao and NK Tiwari
3. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
4. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
5. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.

Reference Books:

1. Remington"s Pharmaceutical Sciences
2. Theory & Practice of Industrial Pharmacy by Lachman
3. 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.

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M.PHARM. IN PHARMACOLOGY

COURSE STRUCTURE SYLLABI

Course Code	ENTREPRENEURSHIP MANAGEMENT	L	T	P	C
21SOE301c	(Elective)	3	0	0	3
	Semester	III			

Course Objectives:

This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management

Course Outcomes (CO): Student will be able to

- 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 Organizing an Enterprise: Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilization -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

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., Toranto.
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