

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY KAKINADA
Syllabus for Pre-Ph. D Examination
Pharmacy

PAPER – II		Subject Code
S. No	Subject	
1	MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES	1307101
2	ADVANCED MEDICINAL CHEMISTRY	1307102
3	BI0-PHARMACEUTICS & PHARMACOKINETICS	1307103
4	ADVANCED PHARMACOLOGY	1307104
5	PHARMACEUTICAL BIOTECHNOLOGY -I	1307105
6	INDUSTRIAL PHARMACOGNOSY	1307106
7	DRUG REGULATORY AFFAIRS	1307107

PAPER – III		Subject Code
S. No	Subject	
1	ADVANCED PHARMACEUTICAL ANALYSIS	1307201
2	ADVANCED CHEMISTRY OF NATURAL PRODUCTS	1307202
3	ADVANCES IN DRUG DELIVERY SYSTEMS	1307203
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PAPER – II

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Unit I

UV-Visible spectroscopy: Introduction, electromagnetic spectrum, absorbance laws and limitations, instrumentation-design and working principle, chromophore concept, auxochromes, Wood-Fisher rules for calculating absorption maximum, applications of UV-Visible spectroscopy

Unit II

IR spectroscopy: Basic principles-Molecular vibrations, vibrational frequency, factors influencing vibrational frequencies, sampling techniques, instrumentation, interpretation of spectra, FT-IR, theory and applications

Unit III

- a. Column Chromatography: Adsorption and partition, theory, preparation, procedure and methods of detection
- b. Thin Layer Chromatography: Theory, preparation, procedures, detection of compounds
- c. Paper Chromatography: Theory, different techniques employed, filter papers used, qualitative and quantitative detection

Unit IV

Gas chromatography: Introduction, fundamentals, instrumentation, columns: preparation and operation, detection, dramatization.

Unit V

HPLC: Principles and instrumentation, solvents and columns used, detection and applications

Unit VI (Research Orientation)

Concept of quality assurance of total quality management, philosophy of GMP, CGMP, GLP and GCP

TEXT BOOKS

- 1) Instrumental Methods of Chemical Analysis by B.K Sharma
- 2) A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
- 3) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
- 4) Pharmaceutical Chemistry by Becket and Stanlake
- 5) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D. Sethi

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6) Pharmaceutical Analysis by Higuchi, Bechmman and Hassan

REFERENCES:

- 1) Organic spectroscopy by Y.R Sharma
- 2) Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
- 3) Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
- 4) Organic Chemistry by I. L. Finar
- 5) Organic spectroscopy by William Kemp
- 6) Quantitative Analysis of Drugs by D. C. Garrett
- 7) Spectrophotometric identification of Organic Compounds by Silverstein
- 8) HPTLC by P.D. Seth
- 9) Indian Pharmacopoeia 2007
- 10) Remington's Pharmaceutical Sciences by Alfonso and Gennaro
- 11) Theory and Practice of Industrial Pharmacy by Lieberman and Lachman
- 12) Indian Pharmacopoeia 1996, 2007
- 13) Instrumental Methods of Chemical Analysis By B.K. Sharma
- 14) A Text Book of Pharmaceutical Analysis by Kerrenth A. Connors
- 15) Journals (Indian Drugs, IJPS etc.)
- 16) Quality Assurance of Pharmaceuticals (A compendium of guidelines and selected materials) Vol. I& II (Pharma Book Syndicate, Book Street, Hyderabad)

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ADVANCED MEDICINAL CHEMISTRY

Unit-I Theoretical Aspects of Drug Action

Types of drug action, Physicochemical parameters and pharmacological activity, Non empirical Electronic parameters, steric parameters and Stereo Chemical aspects of Drugs. Drug Receptors, Receptor types and isolation, Drug Receptor Interaction, theories of drug action, mechanism of drug action.

Unit-II Targets for the development of following chemotherapeutic agents: Anti-tubercular, Anti malarial , Anti – fungal, Immuno- modulators, Anti- amoebic drugs. Targets for the development of following pharmacodynamic agents – Antiulcer, Analgesic – Anti inflammatory, Anti atherosclerotic, Anti- Angiogenesis, anti – hypertensives.

Unit -III

Biotransformation of drugs- Prodrug approach, Soft Drug approach, enzymes responsible for biotransformation, microsomal and non microsomal mechanisms. Factors influencing enzyme induction and inhibition. Design of Local anesthetics, diuretics, Anti- HIV, anticancer, Introduction, general considerations on the development of new drugs, classical and rational procedures for the development of local anesthetics Genesis of New Drugs: Serendipity, Random Screening, Extraction of active principles from Natural Sources, Molecular Modification of Known Drugs, Selection or Synthesis of Soft Drugs, Drug Latentiation and rational drug design

Unit-IV : Rational Drug Design: QSAR: Parameters involved in QSAR, lipophilicity (Polarisability, electronic and steric parameters). Quantitative models. Hansch Analysis, Free Wilson Analysis and their relationships, linear relationships and applications of Hansch and Free Wilson Analysis. Molecular Modeling: Introduction, molecular methods, Known receptors, unknown receptors.

Unit-V: Structure based drug design : Inhibitors of HIV-I Prokinase, Structural studies of HIV-I Reverse transcriptase and implications for drug design, Bradykinin receptor Antagonists, Design of purine nucleoside and Phosphorylase inhibitors, Aldose Reductase Inhibitors, Thrombin inhibitors. Rhinoviral-Capsidbinding Inhibitors.

Unit – VI (Research Orientation)

Design of experiments - Principles, Study of CRD, RBD, LSD and factorial designs, ANOVA

TEXT BOOKS

1. William O Foye Medicinal Chemistry
2. Berger's Medicinal Chemistry and Drug Design. 6th Edition.

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3. Richard B. Silvermann, Org. Chemistry of Drug Design and drug Action.

REFERENCE BOOKS

1. Korolkovas Essentials of Medicinal Chemistry
2. Purcell Strategies of Drug Design
3. Alfred Berger Biochemical Basis of Drug Design
4. Corwin , Hansen Comprehensive Medicinal Chemistry
5. Testa B and Jenner P. Drug Metabolism Chemical & Biochemical Aspects, Marcel Dekker
6. Gyorgy Keri & Istvan Toth Molecular Pathomechanism and New Trends in Drug Research, Taylor & Francis Pub.
7. Ariens. Drug design medicinal chemistry a series of monograph-volume 11- III, academic press, an imprint of Elsevier pub.
8. Structure based Drug Design by Pandi Veerapandion

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BI0-PHARMACEUTICS & PHARMACOKINETICS

Unit I

Bio-availability Bioequivalence and Therapeutic equivalence: Designing of bioavailability studies and interpretation of results. Regulatory requirements.

Unit II

Physicochemical properties affecting bioavailability, pH-partition theory, dissolution, surface area adsorption, complexation, polymorphism and techniques of enhancing dissolution rate. Formulation factors affecting bioavailability of drugs in dosage forms of Tablets, capsules, parenterals, liquid orals and topical dosage forms.

Unit III

Basic concepts of Pharmacokinetics: Compartmental models: One, Two and non-

compartmental approaches to Pharmacokinetics. Recent trends, merits and limitations of these approaches. Application of these models to determine the various pharmacokinetic parameters pertaining to:

- a) Absorption: (wherever applicable) absorption rate constant, Absorption half time, lag time and extent of absorption, AUC.
- b) Distribution: Apparent volume of distribution and its determination.
- c) Metabolism: Metabolic rate constant
- d) Elimination: Overall apparent elimination rate constant and half life under the following conditions:
 - i. Intravenous bolus injection.
 - ii. Intravenous infusion.
 - iii. Single dose oral administration.
 - iv. Multiple dose injections.
 - v. Multiple dosage oral administration
- e) Non invasive methods of estimating Pharmacokinetic parameters with emphasis on salivary and urinary compartments.
- f) Concept of clearance: Organ clearance, total clearance, hepatic clearance, lung clearance and renal clearance.

Unit IV

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Non-linear Pharmacokinetics: Concepts of linear and non linear pharmacokinetics, Michaelis - Menton kinetics characteristics. Basic kinetic parameters, possible causes of non induction, non linear binding, non linearity of pharmacological responses. Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics, chemically induced dependency.

Unit V

Drug Metabolism - sites of metabolism, factors affecting drug metabolism (genetic, species and environmental).

Clinical pharmacokinetics: Altered kinetics in pregnancy, child birth, infants and geriatrics. Kinetics in GI disease, malabsorption syndrome, Liver, cardiac, renal and pulmonary disease states.

Unit – VI (Research Orientation)

Design of experiments - Principles, Study of CRD, RBD, LSD and factorial designs, ANOVA

Text Books:

1. Biopharmaceutics and clinical Pharmacokinetics by Milo Gibaldi.
2. Remington's Pharmaceutical Sciences by Mack publishing company, Pennsylvania.
3. Pharmacokinetics by Milo Gibaldi, Donald Perrier; Marcel Dekker, Inc.
4. Handbook of clinical Pharmacokinetics by Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
5. Biopharmaceutics and Pharmacokinetics by Robert E. Notari.
6. Biopharmaceutics by Swarbrick.
7. Biopharmaceutics and Pharmacokinetics- A Treatise by D.M. Brahmkar and Sunil B. Jaiswal., Vallabh Prakashan Pitampura, Delhi.
8. Clinical Pharmacokinetics, Concepts and Applications by Malcolm Rowland and Thomas N. Tozer. Lea and Febiger, Philadelphia, 1995.
9. Dissolution, Bioavailability and Bioequivalence by Abdou. H.M., Mack Publishing Company, Pennsylvania, 1989.
10. Biopharmaceutics and Clinical Pharmacokinetics- An introduction; 4th edition, Revised and expanded By Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. C. Boylan. Marcel Dekker Inc, New York, 1996.

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ADVANCED PHARMACOLOGY

Unit-I

I. Molecular Pharmacology:

Pharmacology of receptors: Classification, Cellular signaling systems, and pharmacology of agonists and antagonists of the following receptors

- i. Excitatory amino acid receptors
- ii. Purinoreceptors
- iii. GABA and Glycine receptors
- iv. Neurosteroid receptors
- v. Cannaboid receptors
- vi. Melatonin receptors
- vii. Adrenergic receptors
- viii. Cholinergic receptors
- ix. Dopaminergic receptors
- x. Serotonergic receptors

Unit-II

a. Drugs acting on the Central Nervous System.

- b. Drugs used in the treatment of
1. Anxiety & Depression
 2. Psychosis & Mania
 3. Epilepsy
 4. CNS degenerative disorders
 5. Parkinson's Disease

Unit-III

Drugs affecting renal and cardiovascular function.

Diuretics

Renin & Angiotensin

Drugs used in the treatment of

1. Myocardial Ischemia
2. Hypertension
3. CHF
4. Hyperlipidemia

Anticoagulants, Thrombolytics & antiplatelet drugs.

Unit IV

Endogenous Mediators:

a) Histamine b) Prostaglandins c) Leukotrienes, d) Nitric Oxide e) Kinins f) EDRF, EDCF & EDHF g) Opioid Peptides h) 5-HT.

Unit V

- A. Bioassays: Basic principles of Biological standardization: Methods used in the bio-assay of Rabbits Vaccine, Oxytocin, Test for pyrogens, Test for undue toxicity
- B. Toxicity tests: OECD guidelines. Determination of LD50, Acute, subacute and chronic toxicity studies.
- C. Principles of clinical pharmacology and designs for testing of drugs in humans. Clinical Trials- Phases I, II, III, IV.
- D. Stem Cells: Basic concepts and therapeutic applications in medicine.

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Unit VI (Research Orientation)

Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of psychopharmacological, anti-inflammatory, analgesic, anti diabetic, hepatoprotective, nootropic and anti cancer activities. Isolated tissues and their importance in pharmacological screening.

TEXT BOOKS:

1. Pharmacology by H.P Rang M.M, Dale, J.M.Ritter & P.K.Moore
2. The Pharmacological basis of therapeutics by Joel G.Hardman. Lee E Limbird and Alfred Goodman Gilman
3. Screening methods in Pharmacology, Vol.-1&2 by Robert .A. Turner and Peter Hebborn.
4. Basics and Clinical Pharmacology 8th edition edited by Bertram G Katzung.

REFERENCE BOOKS.

1. Pharmacology and Pharmacotherapeutics by R.S Satoskar, S.D Bhandarkar and S.S Ainapure.
 2. Essentials of Medical Pharmacology by K.D.Tripathi
 3. Drug discovery and evaluation by H.G.Vogel and W.H.Vogel, Springer-Verlag, Berlin Heidelberg.
 4. Handbook of experimental pharmacology by S.K. Kulkarni, Vallabh Prakashan, Delhi.
 5. Textbook of clinical trials edited by David Machin, Simon Day and Sylvan green.
- Principles of clinical research edited by Giovanna di ignazio, Di Giovanna and Haynes

PHARMACEUTICAL BIOTECHNOLOGY -I

Unit I

An Introduction process: The range of fermentation process, microbial biomass, microbial enzymes, microbial metabolites, recombinant products, transformation process.

Microbial growth kinetics: Batch cultures, continuous cultures, fed batch cultures, continuous with recycle culture, cascade cultures. The Isolation of industrially important micro organisms, preservation of industrially important micro organisms & improvement of industrially important micro organisms.

Unit II

Media for industrial fermentation: Introduction, types of media. Media formulation: water, carbon source, Energy source, Nitrogen source, minerals, buffers, Precursors, Inhibitors, Inducers, Antifoams, oxygen requirements. Media optimization techniques with special emphasize on statistical techniques, placket-Burman design, response surface methodology. Sterilization: Introduction, Medium sterilization, the design of batch sterilization process, the design of continuous sterilization process, sterilization of fermented, sterilization of the feed, sterilization of liquid wastes and filter sterilization.

Unit III

The development of inocula of Industrial fermentations: Introduction, criteria for the transfer of inoculum, the development of inocula for yeast process, the development of inocula for bacterial process, the development of inocula for mycelia process, the development of inocula for vegetative fungi. The Aseptic inoculation of plant fermented.

Unit IV

Design of a Fermented: Introduction, basic function of fermenter for microbial & Animal cell culture, Aseptic operation & contaminant, overall contaminant categorization, Body construction, Aeration & Agitation, the agitators, baffles, the achievement & maintenance of aseptic condition, valves & steam traps. And other fermentation vessels.

Unit V

Applications of fermentation technology-I: Alcohol (Methanol, Butanol, Ethanol etc), Acids (citric acid, Acetic acid, Gluconic acid etc), Solvents (glycerol, Acetone, Butanol etc).

Applications of fermentation technology-II: Antibiotics (penicillin, Streptomycin, tetracycline) Amino acids (lysine, Glutamic acid), Single Cell Protein, Mineral beneficiation & Oil recovery.

Unit VI (Research Orientation)

Concept of quality assurance of total quality management, philosophy of GMP, CGMP, GLP and GCP

TEXT BOOKS

1. Principles of fermentation technology by Peter F Stanbury, Allan Whitaker and Stephen J Hall, pergamon Publications.
2. Introduction to Biochemical Engineering by Dr. D.G. Rao, the Mc Graw Hill companies.

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Industrial Pharmacognosy

Unit I

General Methods of Isolation, Purification, Identification and Estimation of Phytoconstituents.

Morphine, Quinine, Emetine, Sennosides, Volatile oils.

Unit II

Different Methods (including industrial) for the isolation and estimation of the following phytopharmaceuticals.

- a) Starch b) Caffeine c) Atropine d) Taxol e) Vinca alkaloids
f) Withaferin g) Ergometrine h) Morphine.

Unit III

Applications of HPLC and HPTLC in the isolation, separation and identification of natural products with reference to the following

- a) Vasicine b) Bacoposide c) Solasodine d) Lupeol.

Unit IV

Study of the following herbal extracts for processing and standardization.

- a) Withania somnifera b) Ocimum sanctum c) Adathoda vasica d) Centella asiatica
e) Melia azadirachta.

Unit V

Applications of UV, IR, ¹HNMR, ¹³CNMR and Mass Spectroscopy in the structural elucidation of natural products.

Unit VI (Research orientation)

Chromatographic applications (TLC, PC, HPLC, HPTLC, GLC) in the isolation, separation and purification of natural products.

Text Books:

1. Trease and Evans, Pharmacognosy, Latest Edition.
2. Pharmacognosy by Varro E. Lylor, Lynn R. Brody, James E. Roberts, K. M. Varghese co., Mumbai.
3. T.E. Wallis, Text Book of Pharmacognosy.
4. Diosgenin and other steroid drug precursor by asolkar, CSIR.
5. Steroids by Feiry and Feisher.
6. Alkaloids Chemical and Biological by S W Pelletier.
7. Chromatography of alkaloids by Vapoorte, Swendson.
8. Elements of chromatography by P. K. Lala.
9. Jenkins Quantitative Pharmaceutical chemistry by A. N. Knewell.

References:

1. Clarke's Isolation and Identification of Drugs by A C Mottal.
2. Selected Topics in Exp-Pharmacology by Seth V. K.
3. Phytochemical methods of Chemical Analysis of Harborne.
4. Organic Chemistry vol. II by I. L. Finar.
5. The use of Pharmacological Techniques for the Evaluation of Natural Products by B. N. Dhavan, R. C. Srimal, CDRI Lucknow.
6. Herbal Drugs Industry by R. D. Chaudhri.
7. Herbal Pharmacopoeia.
8. HPLC methods of Drug Analysis by Mantu K Ghosh.

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DRUG REGULATORY AFFAIRS

Unit I

Formulation development: Regulatory requirements involved in the preformulation studies, solid, liquid and semi-solid dosage forms, controlled release preparations, injections, ocular preparations as per the European community, United States and Indian regulatory authorities

Unit II

Manufacturing: Regulatory requirements as per European community, United States and Indian regulatory authorities for manufacturing information, manufacturing formula, process, validation of manufacturing process, equipment, documentation, inspection requirement of regulatory guidelines for active ingredients, data requirement for new drug, International aspects of Excipients, approval as per guidelines of all the territories. Regulatory guidelines for packaging materials, test and evaluation of packaging materials, biological test, elastometer test, microbiological test and evaluation of closures.

Unit III

Stability testing: Scientific and technical background to the design of stability testing regulatory requirements as per European community, United States and Indian regulatory authorities for testing of new active substances, bulk active drug substances, dosage form in their final packaging. Extension of shelf-life after authorization of drug international harmonization and current guidelines. Regulatory affairs in respect of residual solvents as per the ICH guidelines, analytical method validation, pharmacokinetic and toxicokinetic validation.

Unit IV

Preclinical aspects of Biopharmaceutics: Current guidelines and developments as per regulatory requirements of European community, United States and Indian regulatory authorities in respect of clinical bioavailability, study design, presentation documentation and statistical analysis

Unit V

Intellectual property rights and patents: Introduction, purpose, international scenario and Indian scenario, guidelines as per European community, United States and Indian regulatory authorities, documentation, presentation and application, procedure for obtaining and writing a patent and patenting rules and regulations

Unit VI (Research Orientation)

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Clinical pharmacology and Pharmacodynamics: Regulatory guidelines as per European community, United States and Indian regulatory authorities on clinical study design, documentation, presentation and interpretation. Clinical trials: Definition, phase I, phase II, phase III and phase IV studies, design documentation, presentation and interpretation, statistical analysis of clinical data and factorial design.

Text Books:

1. Quality Assurance Guide by Organization of Pharmaceutical producers of India.
2. Drug formulation manual by D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
3. How to practice GMPs by P.P.Sharma. Vandhana Publications, Agra.
4. Pharmaceutical Process Validation by Fra. R. Berry and Robert A. Nash.
5. Pharmaceutical Preformulations by J.J. Wells.
6. Applied production and operations management by Evans, Anderson, Sweeney and Williams.
7. Basic Principles of Clinical Research and Methodology by Gupta.
8. Biopharmaceutics and Clinical Pharmacokinetics-An introduction; 4th edition, Revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.

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PAPER – III

ADVANCED PHARMACEUTICAL ANALYSIS

Unit I

Mass spectroscopy: Theory, ionization techniques: electron impact ionization, chemical ionization, field ionization, fast atom bombardment, plasma desorption, fragmentation process: types of fission, resolution.

Unit II

GC/MS, interpretation of spectra and applications for identification and structure determination

Unit III

NMR: Theory, instrumentation, chemical shift, shielding and deshielding effects, splitting of signals, spin-spin coupling, proton exchange reactions, coupling constant(J), nuclear overhauser effect(NOE), ¹³C NMR spectra and its applications, 2D-NMR, COSY and applications in pharmacy

Unit IV

Counter – current extraction, solid phase extraction techniques, gel filtration. An advanced study of the principles and procedures involved in the electrometric methods: Conductometry, Potentiometry, and Polarography and Amperometry.

Unit V

Principles and procedures involved in using the following reagents in pharmaceutical analysis with suitable examples

- i. MBTH (3-methyl-2- benzothizolone hydrazone)
- ii. F.C. Reagent (Folin-Ciocalteu)
- iii. PDAB (Para Dimethyl Amino Benzaldehyde)
- iv. 2, 3, 5 – Triphenyl tetrazolium salt
- v. 2,6 Dichloroquinone Chlorimide

Unit VI (Research Orientation)

Concepts of Analytical Method Development, validation and calibration of various Analytical Instruments such as UV and visible spectrophotometer, Spectrofluorimeter, HPLC and GC-MS and analytical methods

TEXT BOOKS

- 1) Instrumental Methods of Chemical Analysis by B.K Sharma
- 2) A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
- 3) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
- 4) Pharmaceutical Chemistry by Becket and Stanlake
- 5) Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D. Sethi
- 6) Pharmaceutical Analysis by Higuchi, Bechmman and Hassan

REFERENCES:

- 1) Organic spectroscopy by Y.R Sharma
- 2) Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
- 3) Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
- 4) Organic Chemistry by I. L. Finar

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- 5) Organic spectroscopy by William Kemp
- 6) Quantitative Analysis of Drugs by D. C. Garrett
- 7) Spectrophotometric identification of Organic Compounds by Silverstein
- 8) HPTLC by P.D. Seth
- 9) Indian Pharmacopoeia 2007
- 10) Remington's Pharmaceutical Sciences by Alfonso and Gennaro
- 11) Theory and Practice of Industrial Pharmacy by Lieberman and Lachman
- 12) Indian Pharmacopoeia 1996, 2007
- 13) Instrumental Methods of Chemical Analysis By B.K. Sharma
- 14) A Text Book of Pharmaceutical Analysis by Kerrenth A. Connors
- 15) Journals (Indian Drugs, IJPS etc.)
- 16) Quality Assurance of Pharmaceuticals (A compendium of guidelines and selected materials) Vol. I& II (Pharma Book Syndicate, Book Street, Hyderabad)

ADVANCED CHEMISTRY OF NATURAL PRODUCTS

Unit I

(A) General Methods of Extraction, Qualitative chemical test for the detection of various natural product compounds.

(B) Study of herbal extracts – processing, equipment and analytical profile of extracts of drugs.

Unit II

Isolation/Separation techniques – The technique and application of thin layer chromatography and preparative TLC, column chromatography – medium and high-pressure liquid column chromatography, flash chromatography, HPTLC, HPLC and GC – normal and reverse phase techniques.

Unit III

Alkaloids - Introduction, general methods of structure elucidation, chemistry and structure elucidation of morphine, reserpine and quinine. Isolation procedure of piperine and quinine.

Unit IV

Steroids – Introduction, nomenclature and stereochemistry, chemistry of cardiac glycosides, progesterone, oestradiol, cortisone, testosterone, bile acids, chemistry and structure elucidation of cholesterol, testosterone, progesterone. Synthesis of stilbesterol & hexesterol Isolation procedure of diosgenin and sennosides.

Unit V

Natural Products as Leads for New Drugs Introduction/History, approaches to discovery and development of natural products as potential new drugs, selection and optimization of lead compounds for further developments from CNS, anti cancer, antibiotic and cardiovascular drugs.

Unit VI (Research Orientation)

Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of psychopharmacological, anti-inflammatory, analgesic, anti diabetic, hepatoprotective, nootropic and anti cancer activities. Isolated tissues and their importance in pharmacological screening.

Text Books

1. Organic Chemistry Vol. 2nd by I. L. Finar
2. Org. Chemistry by Morrison & Boyd
3. Alkaloids – Chemical & Biological Prospective by S. W. Pelletier
4. Steroids by Fischer and Fischer

References:

1. Pharmacognosy by Trease & Evans
2. Chemistry of Natural Products – Ata Ur Rehman
3. Natural Products – A Lab Guide by Raphael Ikon
4. Screening methods in Pharmacology, Vol.-1&2 by Robert .A. Turner and Peter Hebborn.

ADVANCES IN DRUG DELIVERY SYSTEMS

Unit I

Fundamentals of controlled drug delivery systems, use of polymers in controlled drug delivery, pharmacokinetic and pharmacodynamic basis of controlled drug delivery.

Factors involved and regulatory requirements

Unit II

Design, fabrication, evaluation and applications of the following controlled release systems.

- a) Controlled release oral drug delivery systems
- b) Parenteral controlled release drug delivery systems
- c) Implantable therapeutic systems

Unit III

- d) Transdermal therapeutic systems and Iontophoresis
- e) Ocular and intrauterine delivery systems
- f) Bioadhesive drug delivery systems
- g) Proteins and peptide drug delivery

Unit IV

Biochemical and molecular biology approaches to controlled drug delivery

- a) Micro particulate drug carriers; Liposomes, Niosomes, Microspheres, Nanoparticles and Resealed erythrocytes.
- b) Monoclonal antibodies

Unit V

Drug targeting to particular organs:

- a) Drug delivery to respiratory system
- b) Problems of drug delivery to the brain and targeting to brain
- c) Drug delivery to eye
- d) Drug targeting in Neoplastic diseases

Unit VI (Research Orientation)

Concept of quality assurance of total quality management, philosophy of GMP, CGMP, GLP and GCP

Text Books:

1. Encyclopedia of controlled delivery; by Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and sons, Inc, New York / Chichester / Weinheim.
2. Controlled and Novel Drug Delivery by N.K.Jain, CBS Publishers and Distributors, New Delhi, First edition, 1997 (reprint in 2001).
3. Controlled Drug Delivery - Concepts and Advances by S.P.Vyas and R.K.Khar, Vallabh Prakashan, New Delhi, First edition, 2002.
4. Remington's Pharmaceutical Sciences.
5. Novel drug delivery system by Y.M.Chien, Marcel Dekker, Inc.
6. Controlled Drug Delivery - Fundamentals and Applications, 2nd edition by Joseph R.Robinson and Vincent H.L.Lee.
7. Pharmaceutical Dosage forms, disperse system: Volume 1, by Herbert A.Libermann et.al, Marcel Dekker, Inc.
8. Pharmaceutical Dosage forms: Tablets Volume II, Herbert A.Libermann et.al, Marcer Dekker, Inc.
9. Bentley's Textbook of Pharmaceutics by E.A.Rawline, ELBS Publications.
10. Microencapsulation and Related Drug Process by Patric B.Deasy.

Unit -I

Drug Absorption: Gastrointestinal, percutaneous and rectal kinetics and factors affecting drug absorption.

Unit -II

Drug distribution: plasma protein binding – factors affecting plasma protein binding – Tissue binding – transfer of drugs through biological barriers their therapeutic implication in drug action.

Elimination of drugs: Concept of renal clearance and excretion of drugs – biological half-life.

Unit -III

Bioavailability of drug products: Bioavailability tests. Reaction of the body to foreign substances: Biotransformation of drugs, phase I and phase II metabolic reactions.

Unit -IV

Microsomal and non-microsomal biotransformation reactions. Drug metabolism in liver, kidney, intestine and placenta. Drug metabolism in fetus and new born. In-Vitro and In-Vivo studies in drug metabolism; metabolic schemes of selected drugs.

Unit -V

Factors influencing drug metabolism: (1) Stereochemical, Physico-chemical and biological factors, (2) Physiological: Species difference, strain difference, sex, age, environment factors, (3) Pathological states, (4) Genetic factors – Pharmacogenetics – heritable factors recognized in man by use of drugs.

Drug interactions: Pharmacokinetic, Pharmacodynamic drug interactions, Food drug and drink interactions.

Unit – VI (Research Orientation)

Design of experiments - Principles, Study of CRD, RBD, LSD and factorial designs, ANOVA

Text Books :

1. Gibaldi, M. and Donald Perrier – Pharmacokinetics Page No. 29/43
2. Rowland, M. and Tozer, T.N. , Clinical Pharmacokinetics – Concepts and applications, Lea and Fibiger, USA
3. Abdou, H.M., Dissolution, Bioavailability and Bioequivalence, Mack Publishing Co. Ltd., Easton, PA
4. Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel, Susanna WU – Pong & Andrew B.C. Yu
5. Principles of Medicinal Chemistry by William O. Foye, Thomas L. Lemke and David A. Williams
6. Wilson and Gisvold's text book of Organic Medicinal and Pharmaceutical Chemistry by Jaime N. Delgado & William A. Remers

References:

1. The Pharmacological basis of therapeutics by Joel G. Hardman, Lee E. Limbird and Alfred Goodman Gilman
2. Principles of Medicinal Chemistry by William O. Foye, Tomas L. Lemke & David A. Williams
3. Pharmacology by H.P. Rang, M.M. Dale, J.M. Ritter & P.K. Moore
4. Essentials of Pharmacotherapeutics by F.S.K. Barar
5. Principles of drug action by Golsteins, Aranow and Kalman.

PHARMACEUTICAL BIOTECHNOLOGY II

Unit I.

Enzymes: Classification and nomenclature, mode and mechanism of enzyme action.

Pharmaceutical

Applications of enzymes. Bacterial enzymes, industrial enzymes and production of enzymes.

Study of

Pharmaceutical and therapeutic enzyme.

Unit - II

Immobilization: Various techniques, immobilization of cells and enzymes. Applications of Immobilization -

enzyme and cell immobilization, its therapeutic applications.

Unit - III

Genetics: Structure of DNA as genetic material, Replication, repair, gene rearrangements, recombination

and transposition, RNA synthesis and splicing. Protein synthesis and targeting. Control of gene

expression in prokaryotes. Eukaryotic chromosomes and gene expressions.

Unit - IV

Recombinant DNA technology: Introduction, mutagenesis, cutting and rejoining. Polymerase chain

reaction,. Isolation and amplification of genes, gene expression genetic recombination:

Transfer of

characters, genetic recombination, phage crosses, and gene transfer mechanism.

Unit -V

Immunology, Monoclonal antibodies and Hybridoma technology: A brief introduction to immunology.

Formation and selection of hybrid cells, principles and productions of monoclonal antibodies, commercial

production, characterisation, quality control and storage of monoclonal antibodies.

Advantages and

applications of monoclonal antibodies.

Unit – VI (Research Orientation)

Tissue culture: Introduction, historical background, preparation of culture media, types of culture,

modification through transformative cell culture, Regeneration of plants. Micropropagation, protoplast microinjection Methods of gene transfer in plants, pharmaceutical applications of plant tissue

culture.

BOOKS RECOMMENDED:

1. Pharmaceutical Biotechnology: Vyas and Dixit.
2. Gene VII: Lewin Benjamin.
3. Industrial Microbiology: L.E. Casida.
4. Biotechnology- The Biological Principles: M.D. Trevan, S. Boffey, K.H. Goulding and P. Stanbury.
5. Microbial Genetics: David Freifelder.
6. Immunology: J. Kuby.
7. Immunology: Weir.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY KAKINADA
Syllabus for Pre-Ph. D Examination
Pharmacy

Herbal Drug Technology and Formulation Development

Unit I

Tissue culture: a) Culture methods b) Organogenesis and embryogenesis
c) Micro propagation d) Haploid culture e) Synthetic seeds f) Immobilization

Unit II

Production of secondary metabolites:

Strategies, use of precursors, growth regulators and elicitors, batch culture and continuous culture, application of new culture method, hair root culture, biotransformation, production of secondary metabolites, taxol, ajmalicine, artemisin.

Unit III

Mutations, Hybridization, Polyploidy of Medicinal Plant and their application.

Unit IV

Biogenesis of penicillin streptomycin and tetracyclines.

Unit V

Manufacturing of the following phytopharmaceuticals.

a) Strychnine b) Emetin c) Quinine d) Morphine e) Cocaine f) Atropine.

Unit VI (Research Orientation)

Concept of quality assurance , total quality management, philosophy of GMP, CGMP, GLP and GCP

Text Books:

1. Quality control methods of Herbal Drugs by Pulok. V. Mukherjee.
2. Trease and Evans, Pharmacognosy, Latest Edition.
3. T.E. Wallis, Text Book of Pharmacognosy.
4. Diosgenin and other steroid drug precursor by Asolkar, CSIR.
5. Steroids by Feiry and Feisher.
6. Alkaloids Chemical and Biological by S W Pelletier.
7. Chromatography of alkaloids by Vapoorte, Swendson.
8. Elements of chromatography by P. K. Lala.
9. Jenkins Quantitative Pharmaceutical chemistry by A. N. Knewell.
10. Pharmacognosy by Varro E. Lylor, Lynn R. Brody, James E. Roberts, K. M. Varghese co., Mumbai.

References:

1. Clarke's Isolation and Identification of Drugs by A C Mottal.
2. Selected Topics in Exp-Pharmacology by Seth V. K.
3. Phytochemical methods of Chemical Analysis of Harborne.
4. Organic Chemistry vol. II by I. L. Finar.
5. The use of Pharmacological Techniques for the Evaluation of Natural Products by B. N. Dhavan, R. C. Srimal, CDRI Lucknow.
6. Herbal Drugs Industry by R. D. Chaudhri.
7. Herbal Pharmacopoeia.
8. HPLC methods of Drug Analysis by Mantu K Ghosh.

QUALITY ASSURANCE OF PHARMACEUTICALS

Unit I

Concept of Quality assurance, total quality management, philosophy of GMP, CGMP and GLP.

Organization and personnel, responsibilities, training hygiene - Premises: Location, design, plan layout, construction, maintenance and sanitation, environmental control, sterile areas, control of contamination.

Unit II

Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place - Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls and raw materials.

Unit III

Manufacture and controls on dosage forms, manufacturing documents master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities - In process quality control on various dosage forms: sterile, biological products and non sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.

Unit IV

Guidelines for Quality Assurance of Human Blood products and large volume parenterals.

Packaging and labeling controls, line clearance and other packaging materials.

Unit - V

Distribution and Distribution records: Handling of returned goods, recovered materials and reprocessing.

Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.

Unit – VI (Research Orientation)

Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities - Finished products release: quality review, quality audits, and batch release document

TEXT BOOKS

1. The International Pharmacopoeia Vol. 1,2,3,4, 3rd edition General methods of analysis quality specifications for Pharmaceutical substances, Excipients, dosage forms.
2. Quality Assurance of Pharmaceuticals: A compendium of guidelines and related material Vol. 1 and Vol. 2., WHO, (1999).
3. GMP-Mehra
4. Pharmaceutical Process validation by Berry and Nash

REFERENCE BOOKS

1. Basic tests for Pharmaceutical substances - WHO (1988)
2. Basic tests for Pharmaceutical substances - WHO (1991)
3. How to practice GMP's – P.P.Sharma
4. The Drugs and Cosmetic Act 1940- Vijay Malik
5. Q.A Manual by D.H.Shah
6. SOP Guidelines by D.H.Shah
7. Quality Assurance Guide by OPPI