Jawaharlal Nehru Technological University

KAKINADA

School of Pharmaceutical Sciences &

Technologies

SYLLABUS FOR M.PHARMACY

Branch: Pharmacology

M.PHARMACY

PHARMACOLOGY

I SEMESTER

Paper 101 – Modern Analytical Techniques
Paper 102 – Pharmacokinetics and Drug Metabolism
Paper 103 – Systemic Pharmacology
Paper 104 - Pharmacokinetics and Drug Metabolism – Practical
Paper 105 – Systemic Pharmacology – Practical
Paper 106 – Seminar
Paper 107 – Assignments

II SEMESTER

Paper 201 – Quality Assurance & Drug Regulatory Affairs
Paper 202 - Biostatistics
Paper 203 – Bioassays & Pharmacological Screening Methods
Paper 204 – Selected topics in Pharmacology
Paper 205 - Bioassays & Pharmacological Screening Methods - Practical
Paper 206 – Seminar
Paper 207 – Assignments

III SEMESTER & IV SEMESTERS

Paper 301 – Seminar – I (On the proposed project work with aims and objectives)
Paper 401 – Seminar – II (On the experimentation and results obtained in the Project work)
Paper 402 – Thesis evaluation
Paper 403 – Defence (Viva – Voce)
Paper 404 – Comprehensive Viva Voce

M.PHARM SYLLABUS FOR PHARMACOLOGY

I SEMESTER

Paper 101: Modern Analytical Techniques
(Instrumental Methods) (Theory)

Principles, instrumentation and applications of the following spectral and magnetic methods of analysis.

a. UV- Visible spectrophotometry
b. Infrared spectroscopy
c. NMR spectroscopy
d. Electron Spin Resonance spectroscopy
e. Atomic Emission spectroscopy
f. Plasma Emission spectroscopy
g. X-Ray diffractometry
h. Optical Rotatory Diffusion
i. Spectrofluorimetry

Principles, instrumentation and applications of the following chromatographic techniques.

a. GLC
b. HPLC
c. HPTLC
d. Exclusion chromatography
e. Super critical fluid chromatography
f. Vapor phase chromatography
g. Affinity chromatography
h. Ion-exchange chromatography

TEXT BOOKS

1. Practical Pharmaceutical Chemistry Vol. 1 &II by Beckett & Stenlake.
2. Instrumental Methods of Analysis by Scog and West.
3. Instrumental Methods of Analysis by B.K.Sharma
4. Vogel's text book of Quantitative Chemical Analysis.
5. Instrumental methods of Analysis by Willard & Merrit.
6. A text book of Pharmaceutical Analysis by K. A. Conners.

REFERENCE BOOKS

1. I.P.
2. B.P.
3. U.S.P.
4. Remington's Pharmaceutical Sciences.
5. Spectroscopy b Silversterin

Paper 102 – Pharmacokinetics and Drug Metabolism

1. Drug Absorption: Gastrointestinal, percutaneous and rectal kinetics and factors affecting drug absorption.
2. Drug distribution: plasma protein binding – factors affecting plasma protein binding – Tissue binding – transfer of drugs through biological barriers their therapeutic implication in drug action.
3. Elimination of drugs: Concept of renal clearance and excretion of drugs – biological half-life.
4. Bioavailability of drug products: Bioavailability tests. Reaction of the body to foreign substances: Biotransformation of drugs, phase I and phase II metabolic reactions.
5. 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.
6. Factors influencing drug metabolism: (1) Steriochemical, 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.
7. Drug interactions: Pharmacokinetic, Pharmacodynamic drug interactions, Food drug and drink interactions.

REFERENCES:

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.

Paper 103 – Systemic Pharmacology

A detailed study of the mechanism of action, Pharmacology and toxicology of drugs acting on : Central nervous system, Autonomic nervous system, Sensory nerves, Cardio Vascular system, Haemopoietic system, Respiratory system, Digestive system, Excretory system, Reproductive system.

A detailed study of the mechanism of action, Pharmacology and toxicology of antinflammatory, antifertility, antidiabetic, antiatherosclerotic, immuno-suppressive drugs, vitamins and chemotherapeutic agents.

REFERENCES:

Pharmacology by H.P. Rang, M.M. Dale, J.M. Ritter & P.K. Moore
Pharmacology and Pharmacotherapeutics by R.S. Satoskar, S.D. Bhandarkar and S.S. Ainapure
Pharmacology (Lippincott's) by Mary J. Mycer, Richard A. Harvey and Pamela C. Champe
Essentials of Medical Pharmacology by K.D. Tripathi
The Pharmacological basis of therapeutics by Joel G. Hardman, Lee E. Limbird and Alfred Goodman Gilman

REFERENCES:

1. Clinical Pharmacy and Therapeutics by Roger Walker and Clive Edwards
2. Clinical Pharmacy by D.R. Laurence, P.N. Bennett and M.J. Brown
3. Clinical Pharmacology by Herphendol

Paper 104 - Pharmacokinetics and Drug Metabolism – Practical

(Practicals based on theory)

Paper 105 – Systemic Pharmacology – Practical

(Practicals based on theory)

II SEMESTER

Paper 201 – Quality Assurance & Drug Regulatory Affairs

1. The concepts of quality assurance, GMP, TQM- Principles and objectives, process control, sources and control of quality variation, statistical quality control, in process quality control, dosage forms control, specifications.
2. GMP- A study of schedule M of Drugs and cosmetics Act, WHO specifications, US FDA guidelines. The study shall include special emphasis on premises, personnel, sanitation, equipment, manufacturing operations and documentation.
3. Validation: Types of validation, protocol for process validation, cleaning validation, validation of air handling, validation of equipment and facilities in sterile and non-sterile areas. Analytical method validation.
4. Ware housing for materials and products; complaints and recalls-evaluation of complaints and recall procedures; finished product release-Quality review-Quality audits – Handling of returned goods, recovered materials and reprocessing.
5. Documentation related to product Development, standard operating procedures, standard test procedures, cleaning methods, quality control documents, batch release document, distribution records, complaints and recalls records, retention of records.
6. Regulatory Affairs – Drugs and Cosmetics Act, DPCO, Intellectual Property Right and Patent laws.
7. New Drug Development and Approval Process:
   Investigational New Drugs (IND), New Drug Applications (NDA), Supplemental New Drug Application (SNDA). ICH requirements for registration of Pharmaceuticals.

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 Mannual by D.H.Shah
6. SOP Guidelines by D.H.Shah
7. Quality Assurance Guide by OPPI

Paper 202 - Biostatistics

1. Tests of significance: Testing hypotheses- principle and applications of Z, t-, F- ratio and chi-square tests in pharmaceutical and medical research.
2. Analyses of Variance: 1-way, 2-way and 3-way classification.
3. Non-parametric tests: sign test, Wilcoxon signed rank test, Wilcoxon sum test, Kruskal Wallis test, run test and median tests.
4. Design of Experiments: Principles of randomization, replication and local control; CRD, RBD, LSD-their applications and analysis of data; Factorial Experiments-Principles and applications; Probit analysis-Dose-effect relationships, calculation of $LD_{50,}$ $ED_{50.}$
5. Regression and correlation: Method of least squares, Correlation Coefficient, rank correlation and multiple regression.

Paper 203 – Bioassays & Pharmacological Screening Methods

1. Principles of Biological standardization: Statistical treatment of modern problems in the biological evaluation of drugs. Methods used in the bio-assay of vitamins, hormones, vaccines, cardiac drugs and other Pharmacopoeial preparations. Test for pyrogens.
2. Bioassay methods for autocoids – development of new bio-assay methods.
3. Toxicity tests: Determination of LD_{50}, Acute, sub acute and chronic toxicity studies – Tests for undue toxicity of drugs.
4. Organization of screening for the Pharmacological activity of new substances with emphasis on the evaluation of antihypertensive, cardiac, Psychopharmacological, autonomic, diuretic, Hepatoprotective, antistress and nootropic activities. Cell culture techniques for Pharmacological screening.

TEXT BOOKS

1. Microbiological assays by Barton J.Wright.
2. Screening methods by Terner.
3. Text book on Pharmacological Screening methods by Vogel's.

REFERENCE BOOKS

I. Pharmacopoeia of India

2. Pharmacopoeial standards for ayurvedic Formulation (Council of Research in Medicine & Homeopathy)

3. Analytical Microbiology by Kavanaagh.F

Paper 204 – Selected topics in Pharmacology

1. Neurohumoral transmission in central and autonomic nervous system: Adrenergic, cholinergic, dopaminergic, serotoninergic, histaminic, GABAergic, glutamate and purinergic systems.
2. Autacoid Pharmacology : A Study of the mechanisms involved in the formation, release, pharmacological actions and possible physiological role of histamine, serotonin, kinins, prostaglandins, opioid autacoids, cyclic 3'-5' AMP, leukotrienes, polypeptides and nitric oxide.
3. Principles of clinical Pharmacology and designs for testing of drugs in humans.
4. Renin – angiotension system its Physiological role Essential Hypertension, Interrelationship between renin angiotension system and sympathetic nervous system – Antagonists of renin – angiotension system.
5. Theories of drug action: Principles of drug action, Ion channels, enzymes. Drug receptor theory: Types of receptors : G-proteins, second messengers and gene therapy.
6. Abnormal actions of drugs such as tolerance, addiction, habituation, idiosyncrasy, allergy, hypersensitivity, adverse drug reactions, antagonism, synergism, potentiation, tachyphylaxis.
7. Principles of drug design, structure activity relationship.

Textbooks:

1. Pharmacology by H.P. Rang, M.M. Dale, J.M. Ritter & P.K. Moore
2. Pharmacology and Pharmacotherapeutics by R.S. Satoskar, S.D. Bhandarkar and S.S. Ainapure
3. Pharmacology (Lippincott's) by Mary J. Mycer, Richard A. Harvey and Pamela C. Champe
4. Essentials of Medical Pharmacology by K.D. Tripathi
5. The Pharmacological basis of therapeutics by Joel G. Hardman, Lee E. Limbird and Alfred Goodman Gilman

REFERENCES:

1. Clinical Pharmacy and Therapeutics by Roger Walker and Clive Edwards
2. Clinical Pharmacy by D.R. Laurence, P.N. Bennett and M.J. Brown
3. Clinical Pharmacology by Herphendol

Paper 205 - Bioassays & Pharmacological Screening Methods – Practical

(Practicals based on theory)

Jawaharlal Nehru Technological University

KAKINADA

School of Pharmaceutical Sciences & Technologies

SYLLABUS FOR M.PHARMACY

Branch: Pharmaceutics

M.PHARM

PHARMACEUTICS

I SEMESTER

Paper CEU 101	**-**	**B10-PHARMACEUTICS & PHARMACOKINETICS**
Paper CEU 102	**-**	**PHYSICAL PHARMACEUTICS**
Paper CEU 103	**-**	**DRUG REGULATORY AFFAIRS**
Paper CEU 104	**-**	**BlO PHARMACEUTICS & PHARMACOKINETICS PRACTICAL EXPERIMENTS BASED ON THEORY.**
Paper CEU 105	**-**	**PHYSICAL PHARMACEUTICS PRACTICALS: PRACTICALS BASED UPON THEORY**.

I SEMESTER

Paper CEU 201	**-**	**ADVANCES IN DRUG DELIVERY SYSTEMS**
Paper CEU 202	**-**	**ADVANCED PHARMACEUTICAL TECHNOLOGY**
Paper CEU 203	**-**	**INDUSTRIAL PHARMACY**
Paper CEU 204	**-**	**ADVANCES IN DRUG DELIVERY SYSTEMS PRACTICALS EXPERIMENTS BASED ON THEORY**
Paper CEU 205	**-**	**ADVANCED PHARMACEUTICAL TECHNOLOGY PRACTICALS EXPERIMENTS BASED UPON THEORY**

III SEMESTER & IV SEMESTER

Paper CEU 301	**-**	**Seminar-I (On the proposed project work with aims and objectives)**
Paper CEU 401	**-**	**Seminar-II (On the experimentation and results obtained in the project work)**
Paper CEU 402	**-**	**Thesis evaluation**
Paper CEU 403	**-**	**Defence (Viva-Voice)**
Paper CEU 404	**-**	**Comprehensive Viva voice**

M.PHARM (PHARMACEUTICS)

I Semester

CEU 101 B10-PHARMACEUTICS & PHARMACOKINETICS

1. Bio-availability Bioequivalence and Therapeutic equivalence: Designing of bioavailability studies and interpretation of results.
2. Physicochemical properties affecting bioavailability, pH-partition theory, dissolution, surface area adsorption, complexion, polymorphism and techniques of enhancing dissolution rate.
3. Formulation factors affecting bioavailability of drugs in dosage forms of Tablets, capsules, parenterals, liquid orals and topical dosage forms.
4. 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: Over all 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.
5. 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.
6. Time dependent pharmacokinetics: Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics, chemically induced dependency.
7. Drug Metabolism - sites of metabolism, factors affecting drug metabolism (genetic, species and environmental).

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

9 Drug interactions: Kinetics of drug interaction, study of drug-drug interactions mediated through absorption, distribution, metabolism and elimination, mechanisms of interaction and consequence. Influence of alcohol, smoking, food and beverages on drug action.

References:

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. Biopharmaceuties and Pharmacokinetics- A Treatise by D.M.Brahmankar 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.

CEU-102 PHYSICAL PHARMACEUTICS:

1. Particle science and powder technology: Crystal structure, Amorphous state, Polymorphism, particle size distribution, particle size analysis methods. Solid dispersions/solid solutions.
2. Physics of tablet compression: Compression, consolidation strength of granules, compression and consolidation under high loads, effect of friction, distribution of forces in compaction, force volume relationships, Heckel plots, compaction profiles, energy involved in compaction, strength of tablet, crushing strength, friability, lamination, instrumentation of tablet machines.
3. Dissolution and solubility: Solubility and solubilisation of non electrolytes, solubilisation by the use of surfactants, cosolvents, complexation, drug derivatisation and solid state manipulation, dissolution rates of solids in liquids, measurement of dissolution rates
4. Theories on stability of disperse systems: Adsorption, wetting, crystal growth mechanisms, physical stability of suspensions and emulsions, stability testing of emulsions and suspension and release of drugs from suspensions and emulsion formulations. Biopharmaceutical aspects of disperse systems.
5. Rheology: Theoretical consideration, instrumentation, rheological properties of disperse systems and semi solids.
6. Polymer science: Properties of polymers, thermodynamics of polymer solution, phase separation, polymers in solid state, applications of polymers in pharmaceutical formulations
7. Kinetics and drug stability: stability calculations, rate equation, Complex order Kinetics, kinetics of some decompositions, strategy of stability testing, methods of stabilization, methods of accelerated stability testing in dosage forms, Freeze-Thaw methods, centrifugal methods, temperature and humidity control, Physical stability testing of pharmaceutical products.
8. Physical properties, instrumental analysis of drug molecules, Differential Thermal Analysis, Differential Scanning Calorimetry, Diffusive Reflective Spectrophotometry, X-Ray Diffraction Analysis.

References:

1. Physical Pharmacy; By Alfred martin
2. Remington's Pharmaceutical Sciences.
3. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann.
4. Pharmaceutical Preformulations; By J.J. Wells.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Instrumental Methods of Chemical Analysis – B. K. Sharma - 9th Edition.
7. Principles of Instrumental Analysis by Donglas A. Skoog, James, J. Leary, 4th Edition.

CEU 103 DRUG REGULATORY AFFAIRS:

1. 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
2. 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.
3. 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.
4. Biopharmaceutics: Different testing parameters and standards as per regulatory requirements of European community, United States and Indian regulatory authorities with respect to factors related to formulation, dosage form, manufacturing process, stability and storage.
5. 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
6. 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.
7. 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

Reference:

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.

CEU 104 BlO PHARMACEUTICS & PHARMACOKINETICS PRACTICAL EXPERIMENTS BASED ON THEORY.

CEU -105 PHYSICAL PHARMACEUTICS PRACTICALS:
PRACTICALS BASED UPON THEORY.

2nd SEMESTER

CEU 201 ADVANCES IN DRUG DELIVERY SYSTEMS

1. Fundamentals of controlled drug delivery systems, use of polymers in controlled drug delivery, pharmacokinetic and pharmacodynamic basis of controlled drug delivery. 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
   d) Transdermal therapeutic systems and Iontophoresis
   e) Ocular and intrauterine delivery systems
   f) Bioadhesive drug delivery systems
   g) Proteins and peptide drug delivery
2. Biochemical and molecular biology approaches to controlled drug delivery
   a) Micro particulate drug carriers; Liposomes, Niosomes, Microspheres, Nanoparticles and Resealed erythrocytes.
   b) Monocional antibodies
3. 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
4. Drug carrier systems targeted to widely dispersed cells
   a) Delivery to Macrophages
   b) Delivery to lymphoid cells of immune network
   c) Delivery to lysosomal storage diseases

References:

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.

CEU-202 ADVANCED PHARMACEUTICAL TECHNOLOGY:

1. Preformulation studies: Goal of preformulation, preformulation parameters, Methodology, Solid state properties, Solubility & partition coefficient, Drug-Excipient compatibility.
2. Formulation Development:
   a) Solid dosage forms:
      Improved production techniques for tablets: New materials, processess, equipments improvements, high shear mixers, compression machines, coating machines, Coating techniques in tablet technology for product development, Physics of tablet compression and computerization for in process quality control of tablets.
   b) Powder dosage forms:
      Formulation development and manufacture of powder dosage from for internal and external use including inhalation dosage forms.
   c) Liquid and Semi-solid dosage forms:
      Recent advances in formulation aspects and manufacturing of monophasic dosage forms, recent advances in formulation aspect and manufacturing of suspensions and semi-solid dosage forms.
   d) Parenteral dosage forms:
      Advances in materials & production techniques, filling machines, sterilizers & aseptic processing
   e) Aerosols:
      Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers & formulation aspects in aerosol formulation, Manufacture & quality control.
3. Aseptic processing operation:
   Introduction, Contamination control, Microbial environmental monitoring, Microbiological testing of water, Microbiological air testing, Characterization of aseptic process, Media and incubation condition, Theoretical evaluation of aseptic operations.

References:

1. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann.
2. Modern Pharmaceutics by Gillbert and S. Banker.
3. Remington's Pharmaceutical Sciences.
4. Pharmaceutical Preformulations by J.J. Wells.
5. Advances in Pharmaceutical Sciences Vol. 1-5 by H.S. Bean & A.H. Beckett.

CEU 203 INDUSTRIAL PHARMACY

1 A detailed study involving machinery and theory of pharmaceutical unit operations like Milling, Mixing, Filtration, Drying and Sterilization.

2 Materials of construction of pharmaceutical equipment and packaging materials. Study of the principles, production techniques and scale up techniques in the large scale production of tablets, capsules, emulsions, suspensions, sterile products, Semisolids and liquid pharmaceuticals, ophthalmic products.

3 Production Management: Production organization, objectives and policies, good manufacturing practices, layout of buildings, services, equipment and their maintenance, materials management, handling and transportation, inventory management and control, production and planning control. Sales forecasting, budget and cost control, industrial and personal relationship.

4 Quality control, Process and Dosage form: Process control, control of manufacturing process, statistical quality control, control charts of automated process control, dosage form control, testing programme and method, product identification system, adulteration and misbranding , drug information profile.

5 Process Validation: Regulatory basis, Validation of solid dosage forms, sterile products, liquid dosage forms. Process validation of raw materials, Validation of analytical methods, Equipment and Process.

References:

1. Theory and Practice of Industrial Pharmacy by Lachmann and Libermann.
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2 by Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2 by Leon Lachmann.
5. Modern Pharmaceutics by Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5 by H.S. Bean & A.H. Beckett.
8. Physical Pharmacy by Alfred martin
9. Bentley's Textbook of Pharmaceutics – Rawbins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition by Sidney H. Willig.
11. Quality Assurance Guide by Organization of Pharmaceutical producers of India.
12. Drug formulation manual by D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation by Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations by J.J. Wells.
16. Applied production and operations management by Evans, Anderson, Sweeney and Williams.

CEU 204 ADVANCES IN DRUG DELIVERY SYSTEMS PRACTICALS EXPERIMENTS BASED ON THEORY

CEU-205 ADVANCED PHARMACEUTICAL TECHNOLOGY PRACTICALS EXPERIMENTS BASED UPON THEORY

Jawaharlal Nehru Technological University

KAKINADA

School of Pharmaceutical Sciences & Technologies

SYLLABUS FOR M.PHARMACY

Branch: Pharmaceutical Analysis and Quality Assurance

M.PHARM

PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE

I SEMESTER

Paper 101 - Advanced Pharmaceutical Analysis - I
Paper 102 - Chromatographic and Other Special techniques
Paper 103 - Quality Assurance of Pharmaceuticals - I
Paper 104 - Advanced Pharmaceutical Analysis-I Practical
Paper 105 - Chromatographic and Other Special techniques Practical
Paper 106 - Seminar
Paper 107 - Assignments

II SEMESTER

Paper 201 - Advanced Pharmaceutical Analysis - II
Paper 202 - Phytopharmaceutical and Biological Analysis
Paper 203 - Quality Assurance of Pharmaceuticals - II (Regulatory Affairs and Patent Laws)
Paper 204 - Advanced Pharmaceutical Analysis - II Practical
Paper 205 - Phytopharmaceutical and Biological Analysis Practical
Paper 206 - Seminar
Paper 207 - Assignments

III SEMESTER & IV SEMESTERS

Paper 301 - Seminar - I (On the proposed project work with aims and objectives)
Paper 401 - Seminar - II (On the experimentation and results obtained in the project Work)
Paper 402 - Thesis evaluation
Paper 403 - Defence (Viva - Voce)
Paper 404 - Comprehensive Viva Voce

M.PHARM SYLLABUS FOR PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE

I SEMESTER

PAPER 101: ADVANCED PHARMACEUTICAL ANALYSIS-I

1. Good Laboratory practices (GLP), Laboratory maintenance, standard operating procedures (SOPS), Validation of analytical instruments and methods.
2. Theory, Instrumentation and application with regard to drug analysis, decomposition product identification and estimation and metabolite analysis based on the following:
    a) Ultraviolet visible spectrophotometry
    b) Infrared Spectrophotometry
    c) Fluoremetry, Nephelometry and Turbidimetry
    d) Paleography.
3. Flame emission spectroscopy and atomic absorption spectroscopy. Principle, Instrumentation and applications in Pharmacy.
4. Thermal methods of analysis: Theory of Thermo gravimetric analysis (TGA), Differential Thermal analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA).
5. An advanced study of non - aqueous titrations involving the following:
    a) Primary, Secondary and Tertiary amines
    b) Halogenated salts and bases
    c) Acidic substances
    d) Assays of official drugs in IP 1996 by non - aqueous titrimetry
    e) Aquametry: Determination of water by titration with Karl Fischer Reagent (KFR).
6. Principles and pharmaceutical applications of redox titrations involving:
    a) Potassium lodate / bromate titrations
    b) Ceric ammonium sulphate titrations
    c) Tanus Chloride titration
    d) Examples of assays of official drugs in IP 1996.
7. Principles and Pharmaceutical applications of complexometric titrations involving:
    a) Direct titration of Polymetallic system with Sodium EDTA
    b) Back titration with sodium EDTA
    c) titration involving the displacement of one complex by another

d) PM indicators
e) Examples of assays official drugs in IP 1996.

8. Statistical Analysis of Data, Methods of Precision, Accuracy, Fuedicial limits, Significance-ratio, Test Chi-Square test, Standard Error, t-test, ANOVA, Correlation Regression Analysis.

PAPER 102: CHROMATOGRAPHIC AND OTHER SPECIAL. TECHNIQUES

An advanced study of the following and their applications.

1. Basic principle and separation by Column chromatography, thin layer chromatography, paper chromatography and ion exchange chromatography.
2. Gas Chromatography: Introduction, theory, column operation, instrumentation and detection, GCMS.
3. High Pressure Liquid Chromatography: Principle, Instrumentation procedure, solvents used, elution techniques, LCMS and applications.
4. HPTLC and Supercritical Fluid Chromatography (SFC): Principle, instrumentation procedure, elution technique and pharmaceutical applications.
5. Electrophoreses (gel and capillary)
6. H.P.T.L.C
7. H.P.C.P.C
8. Radio immuno assay and related immuno assays — RIA, ELISA

PAPER 103: QUALITY ASSURANCE OF PHARMACEUT1CALS- I

1. Concept of Quality assurance, total quality management, philosophy of GMP, CGMP andGLP.
2. Organization and personnel, responsibilities, training hygiene - Premises: Location, design, plan layout, construction, maintenance and sanitations, environmental control, sterile areas, control of contamination.
3. 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.
4. 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.
   Guidelines for Quality Assurance of Human Blood products and large volume parenterals.
5. Packaging and labeling controls, line clearance and other packaging materials.
6. 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.
7. Distribution and Distribution records: Handling of returned goods, recovered materials and reprocessing.
8. Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.

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 Mannual by D.H.Shah
6. SOP Guidelines by D.H.Shah
7. Quality Assurance Guide by OPPI

PAPER 104: ADVANCED PHARMACEUTICAL ANALYSIS –I

1. Use of spectrophotometer for analysis of Pharmacopoeial compounds and their formulations.
2. Use of fIuorimeter for analysis of Pharmacopoeial compounds.
3. Use of Flame photometer for analysis of Na, K & Ca etc in Biological fluids and formulations.
4. Use of Nephelo- Turbidimetric analysis of dispersions and limit tests.
5. Assays involving following procedures: Non – Aqueous, Diazotisation, Complexation and Redox titrations.
6. Official (I.P) Assays based on theory.

TEXT BOOKS

1. Practical Pharmaceutical Chemistry Vol. 1 &II by Beckett & Stenlake.
2. Instrumental Methods of Analysis by Scog and West.
3. Instrumental Methods of Analysis by B.K.Sharma
4. Vogel's text book of Quantitative Chemical Analysis.
5. Instrumental methods of Analysis by Willard & Merrit.
6. A text book of Pharmaceutical Analysis by K. A. Conners.

REFERENCE BOOKS

1. I.P.
2. B.P.
3. U.S.P.
4. Remington's Pharmaceutical Sciences.
5. Spectroscopy b Silversterin

PAPER 105: CHROMATOGRAPHIC AND OTHER SPECIAL TECHN1QUES PRACTICAL

1. Experiments on Electrophoresis.
2. Experiments of Chromatography:
    a) Ascending technique
    b) Descending technique
    c) Circular technique
    3. Experiments using HPLC & GC.

TEXT BOOKS

1. Instrumental Methods of Analysis by Scog and West.
2. lnstrumental Mcthods of Analysis by B.K.Sharma
3. Instrumental methods of Analysis by Willard & Merrit.
4. High Performance Liquid Chromatography by P. D. Sethy.

REFERENCE BOOKS

1. USP
2. Remington's Pharmaceutical Sciences.
3. Spectroscopy by Silversterin
4. Instrumental methods of Analysis by Hibart. H. Willard.

II SEMESTER

PAPER 201 - ADVANCED PHARMACEUTICAL ANALYSIS-II

1. A detailed study of the principles, instrumentation and applications of the following instrumental analysis:
    i. Nuclearinagnetic resonance spectrometry with special reference to 13c NMR.
    ii. Mass spectroscopy.

2 A detailed study of the principles, instrumentation and applications of the following instrumental analysis:
    i. X-ray fluorescence spectrometry
    ii. X-ray diffraction
    iii. Optical rotating dispersion.

3. A detailed study of the principles, instrumentation and applications of the following instrumental analysis:
    i. Raman Spectroscopy
    ii. Inductively coupled plasma - atomic emission spectroscopy
    iii. Electron spin resonance spectroscopy (ESR)
    iv. Advanced chromatographic techniques like Super Critical Fluid Chromatography, Size Exclusion Chromatography

4. A detailed study of the various principles and procedures involved in the qualitative and quantitative analysis of pharmaceutical preparations and dosage forms containing the
following groups of drugs included in IP (Biological and microbiological methods excluded)
    a) Analgesics and antipyietics b) l3arbiturates c) Sulphonamidcs
    d) Antibiotics e) Steroidal hormones f) Vitamins
    g) Alkaloids

5. A detailed study of the principles and procedures involved in the qualitative and quantitative analysis of pharmaceutical preparations and dosage forms using the following reagents and reactions.
    i) Oxidative coupling reactions using MBTH (3 - methyl -2 benzothiazolinone hydrazone hydrochloride)
    ii) Diazotisation followed by coupling
    iii) Oxidation followed by complexation.

6. A detailed study of the principles and procedures involved in the qualitative and quantitative analysis of pharmaceutical preparations and dosage form using the following reagents and reactions
   i) Oxidation followed by charge transfer reaction.
   ii) Condensation reactions using the reagents Para Dimethyl Amino Benzaldehyde (PDAB), Para Dimethyl Amino Cinnamaldehyde (PDAC), Folin's reagent and Gibb's reagent
   iii) Folin-ciocalteu reagent (FC reagent)
7. General methods for quality control of various types of official formulation- tablets, capsules, suspensions, ointments and injections.
8. Testing of containers and closures (glass, metal, rubber and plastic) for pharmaceutical preparations as per the I.P.

TEXT BOOKS

1. Instrumental methods of analysis by Scog and West.
2. Chemical Analysis - Modem Instrumentation methods and techniques by Wiley.
3. Instrumental methods of analysis by Willard Dean & Merrit.
4. A text book of Pharmaceutical Analysis by K.A. Conners (John Wiley)
5. Pharmaceutical analysis edited by Highuchi and Brochman

REFERENCE BOOKS

1. Spectrometric identification of organic compounds by Silverstein (7th Edition) 1981
2. Hand book of Instrumental techniques for analtica1 chemistry edited by Frank sett by Prentice Hall Ine.
3. IP
4. BP
5. USP

PAPER 202 - PHYTOPHARMACEUTICAL AND BIOLOGICAL ANALYSIS

1. Methods of systematic phytochemical analysis including extraction and identification of constituents using chromatographic techniques.
2. Quality control of crude drugs: proximate analysis including ash and extractive values, fiber content, U.V and fluorescence analysis of powdered drugs.
3. Qualitative and quantitative microscopy and chemical microscopy and micro chemical tests.

4. Detection of common adulterants and insects infestation in whole and powdered drugs.
5. Blind screening and screening methods for analgesic, antipyretic, anti-inflammatory and anti
-diabetic activities.
6. Analysis of official formulations derived from crude drugs including some ayurvedic preparations.
7. Microbiological screening methods for antimicrobial activity.
8. Official (IP) Bio assays and Toxicity studies as per IP 1985: Test for histamine like substances, test for pyrogens, test for undue toxicity.

TEXT BOOKS

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Titler, Brady & Robber.
3. Phytochemical methods by J.B.Haroborne.
4. Instrumental methods of Analysis by Willard, Meritt, Dean.
4. The Quantitative analysis of Drugs by D.C.Garat
5. Microbiological assays by Barton J.Wright.

REFERENCE BOOKS

I. Pharmacopoeia of India
2. Pharmacopoeial standards for ayurvedic Formulation (Council of Research in Medicine & Homeopathy)
3. Application of absorption spectroscopy in Organic compounds by J.R.Dyer.
4. Analytical Microbiology by Kavanaagh.F

PAPER 203 - QUALITY ASSURANCE OF PHARMACEUTICALS -II (REGULATORY AFFAIRS AND PATENT LAWS)

1. **Formulations 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.
2. **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.

3. **Regulatory guidelines** for packaging materials, test and evaluation of packaging materials, biological test. Elastometer test, microbiological test and evaluation of closures.
4. **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.
5. **Bio Pharmaceutics:** Different testing parameters and standards as per regulatory requirements of European community, United States and Indian regulatory authorities with respect to factors related to formulation, dosage form manufacturing process, stability and storage.
6. **Preclinical aspects of Biopharmaceutics:** Current guidelines and developments as per regulatory requirements of European community, Unites States and Indian regulatory authorities in respect of clinical bioavailability, study design presentation, documentation and statistical analysis.
7. **Clinical Pharmacology and Pharmacodynamics:** Regulators 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.

8. **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.

TEXT BOOKS

1. FDA Regulatory affairs by Douglas J.Pisano, David Mantus
2. Quality Assurance of Pharmaceuticals by WHO, Geneva Vol-I
3. Quality Assurance of Pharmaceuticals, Vol – II, by W.H.O, Geneva
4. PATENTS by N.R.Subbaram
5.Packaging - specifications, purchasing & quality control by Edmund.A.Leoncard.
6. How to practice G.M.P's — P.P.Sharma
7. Guidelines on CGMP & quality of Pharmaceutical products by S.lyer.
8. Validation standard operating procedures by Syed Imtiaz Ilaider.
9. SOP guidelines by D.H.Shah

REFERENCES:

Publications by Regulatory Authorities of various countries

PAPER 204 ADVANCED PHARMACEUTICAL ANALYSIS -II PRACTICAL

1. Estimation of following classification of drugs using different analytical methods.

a) Analgesics and Antipyretics b) Barbiturates c) Sulfonamide drugs

d) Antibiotics e) Steroidal hormones f) Vitamins

g) Alkaloids

2. Estimation of different classification of drugs using the following reagents:

a) MBTH b) PC reagent c) $FeCl_3$ and 1,10-phenanthroline d) $FeCl_3$ & K_3 Fe $(CN)_6$ e) BM reagent f) p-dimethylamine benzaldehyde g) p-dimethylamino cinnamaldehyde h) N-bromo succinimide- metol/sulphanilamide.

3. Quality control test for official formulations.

4. Testing of containers and closures (glass, metal, rubber and plastic) for official (IP) pharmaceutical preparations.

PAPER 205- PHYTOPHARMACEUTICAL AND BIOLOGICAL ANALYSIS PRACTICAL

1. Spectrophotometric determination of caffeine from tea powder.
2. The estimation of curcumin from Curcuma longa by Spectrophotometric methods.
3. Determination of sugars by descending paper chromatography.
4. Determination of bitterness value of crude drugs.
5. Determination of extractive values of crude thugs.
6. Fluorometric analysis of iso-quinoline alkaloids.
7. Determination of R_f values of different amino acids and alkaloids.
8. Anti - microbial activity of some plant extracts using different pathogenic and non -pathogenic organisms.
9. Colorimetric analysis of some plant drugs.
10. Blind Screening.
11. Screening for analgesic and anti-inflammatory activities.