M.PHARMACY

PHARMACEUTICS

I SEMESTER

Paper 101 - Modern Analytical Techniques
Paper 102 - Research Methodologies
Paper 103 - Biopharmaceutics & Pharmacokinetics
Paper 104 - Advanced Physical Pharmaceutics
Paper 105 - Biopharmaceutics & Pharmacokinetics - LAB
Paper 106 - Advanced Physical Pharmaceutics - LAB
Paper 107 - Seminar

II SEMESTER

Paper 201 - Advanced Pharmaceutical Technology
Paper 202 - Advances In Drug Delivery Systems
Paper 203 - Industrial Pharmacy
Paper 204 - Drug Regulatory Affairs
Paper 205 - Advanced Pharmaceutical Technology - LAB
Paper 206 - Advances In Drug Delivery Systems - LAB
Paper 207 - Seminar

III SEMESTER

Paper 301 - Project Seminar-I (On the proposed project work with aims and objectives) - 50 Marks
Paper 302 - Project work - I

IV SEMESTER

Paper 401 - Project Seminar-II (On the experimentation and results of the project work) – 50 Marks
Paper 402 - Project work - II

SCHEME OF INSTRUCTIONS AND EVALUATION

PHARMACEUTICS

FIRST SEMESTER

Paper No.	Title of the Paper	Evaluation / Marks				Total	Credits
		Theory		Practical			
		Mid Examination	University End Examination	Mid Examination	University End Examination		
Paper – 101	Modern Analytical Techniques	40	60			100	3
Paper – 102	Research Methodologies	40	60			100	3
Paper – 103	Biopharmaceutics & Pharcokinetics	40	60			100	3
Paper – 104	Advanced Physical Pharmaceutics	40	60			100	3
Paper – 105	Biopharmaceutics & Pharcokinetics			40	60	100	2
Paper – 106	Advanced Physical Pharmaceutics			40	60	100	2
Paper – 107	Seminar					100	2
	TOTAL					700	18

SECOND SEMESTER

Paper No.	Title of the Paper	Evaluation / Marks				Total	Credits
		Theory		Practical			
		Mid Examination	University End Examination	Mid Examination	University End Examination		
Paper – 201	Advanced Pharmaceutical Technology	40	60			100	3
Paper –202	Advances in Drug Delivery Systems	40	60			100	3
Paper – 203	Industrial Pharmacy	40	60			100	3
Paper – 204	Drug Regulatory affairs	40	60			100	3
Paper – 205	Advanced Pharmaceutical Technology			40	60	100	2
Paper – 206	Advances in Drug Delivery Systems			40	60	100	2
Paper – 207	Seminar					100	2
	TOTAL					700	18

THIRD AND FOURTH SEMESTERS

Paper No.	III Semester	Total	Credits ***
Paper - 301	Project Seminar – I (On the proposed project work with aims and objectives)	50	2
Paper - 302	Project work - I	----	20
	Total	50	22

Paper No.	IV Semester	Total	Credits ***
Paper - 401	Project Seminar – II (On the Completed project work)	50	2
Paper - 402	Project work - II	---	20
	TOTAL MARKS	50	22
	GRAND TOTAL FOR THE COURSE	1500	80

M.PHARM (PHARMACEUTICS)

I Semester

PAPPER 101 - MODERN ANALYTICAL TECHNIQUES
(Paper Common for all Specializations)

Principles, instrumentation and applications of the following Instruments and Chromatography techniques

Unit- I

i. UV- Visible spectrophotometry
ii. Infrared spectroscopy
iii. Spectrofluorimetry

Unit- II

i. NMR spectroscopy
ii. Electron Spin Resonance spectroscopy
iii. Atomic Emission spectroscopy

Unit- III

i. HPLC
ii. HPTLC
iii. Exclusion chromatography
iv. Super critical fluid chromatography

Unit- IV

i. Mass Spectroscopy including LCMS & GCMS
ii. GLC

Unit- V

i. Plasma Emission spectroscopy
ii. X-Ray diffractometry
iii. Optical Rotatory Diffusion
iv. Vapor phase chromatography
v. Affinity chromatography
vi. 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 -RESEARCH METHODOLOGIES
(Paper common for all Specializations)

UNIT I

Statistical Methods:

Chance Variation – Probability Distribution - Normal Distribution – Sampling Distribution

Error and its significance-Measures of Error- Control of Error in Experimental Investigations – Problem Solving.

UNIT II

Correlation and Regression., Multiple Regression - Problem Solving

UNIT III

Tests of Significance: Principles, t-test, z-test, F-ratio test, Chi-square test, Non-parametric tests- their applications in pharmacy research with examples – Problem Solving

UNIT IV

Design of Experiments

Criteria of a good design with examples.

Principles- Randomization, replication and local control.

Study of CRD, RBD, LSD and factorial designs- their applications in Pharmacy research with examples – Problem Solving

UNIT V

Analysis of Variance (ANOVA) – one way, two way and three way – principles and applications in pharmacy research- Problem Solving

Optimisation Techniques : Optimisation Techniques based on Factorial Experiments - Problem Solving.

Text & Referrence Books :

1. Fundamentals of Biostatistics by Khan & Khanum,Third Revised Edition, Ukaaz Publications, Hyderabad
2. Theory & Practice of Industrial Pharmacy by Leon Lachman and Others
3. Remingtons Practice of Pharmaceutical sciences, (Latest Edition)
4. Principles of Biostatistics by Marcello Pagnano, Published by Brooks/Cole, (Saurabh Printers Pvt. Ltd)

PAPER 103 - BI0PHARMACEUTICS & PHARMACOKINETICS

Unit - I

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

Physicochemical properties affecting bioavailability, pH-partition theory, dissolution, surface area adsorption, complexion, 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 - II

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.

Unit - III

Elimination: Over all apparent elimination rate constant and half life under the following conditions:

i. Single dose oral administration.

ii. Multiple dose injections.

iii. Multiple dosage oral administration

Non invasive methods of estimating Pharmacokinetic parameters with emphasis on salivary and urinary compartments.

Concept of clearance: Organ clearance, total clearance, hepatic clearance, lung clearance and renal clearance.

Unit - IV

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.

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

Unit - V

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

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.

PAPER 104 - ADVANCED PHYSICAL PHARMACEUTICS

Unit – I

Particle science and powder technology: Crystal structure, Amorphous state, Polymorphism, particle size distribution, particle size analysis methods. Solid dispersions/solid solutions.
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.

Unit - II

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
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.

Unit - III

Rheology: Theoretical consideration, instrumentation, rheological properties of disperse systems and semi solids.
Polymer science: Properties of polymers, thermodynamics of polymer solution, phase separation, polymers in solid state, applications of polymers in pharmaceutical formulations

Unit - IV

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.

Unit – V

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.

PAPER 105 - BIO PHARMACEUTICS & PHARMACOKINETICS LAB
(Experiments based on Theory)

PAPER 106 - ADVANCED PHYSICAL PHARMACEUTICS LAB
(Experiments based on theory)

II SEMESTER

PAPER 201 - ADVANCED PHARMACEUTICAL TECHNOLOGY

UNIT- I

Preformulation studies: Goal of preformulation, preformulation parameters, Methodology, Solid state properties, Solubility & partition coefficient, Drug-Excipient compatibility.

UNIT- II

Formulation Development of 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.

Formulation Development of Powder dosage forms:

Formulation development and manufacture of powder dosage from for internal and external use including inhalation dosage forms.

UNIT- III

Formulation Development of 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.

UNIT- IV

Formulation Development of Parenteral dosage forms:

Advances in materials & production techniques, filling machines, sterilizers & aseptic processing

Formulation Development of Aerosols:

Advances in propellants, metered dose inhaler designs, dry powder inhalers, selection of containers & formulation aspects in aerosol formulation, Manufacture & quality control.

UNIT- V

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.

PAPER 202 - ADVANCES IN DRUG DELIVERY SYSTEMS

UNIT- I

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

UNIT- II

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

UNIT- III

Biochemical and molecular biology approaches to controlled drug delivery
   a) Micro particulate drug carriers; Liposomes, Niosomes, Microspheres, Nanoparticles and Resealed erythrocytes.
   b) Monocional antibodies

UNIT- IV

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- V

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.

PAPER 203 - INDUSTRIAL PHARMACY

UNIT- I

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

UNIT- II

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.

UNIT- III

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.

UNIT- IV

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.

UNIT- V

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.

PAPER 204 - DRUG REGULATORY AFFAIRS
(Paper Common for all Specializations)

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.

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.

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

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.

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

References:

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 205 - ADVANCED PHARMACEUTICAL TECHNOLOGY LAB (Experiments Based on Theory)

CEU206 - ADVANCES IN DRUG DELIVERY SYSTEMS LAB (Experiments Based on Theory)