

ANNA UNIVERSITY TIRUCHIRAPPALLI**Tiruchirappalli – 620 024****Regulations 2008****Curriculum****MASTER OF PHARMACY - PHARMACEUTICS****SEMESTER I**

S.No.	Subject Code	Subject	L	T	P	C
Theory						
1	PA9101	Modern Methods of Pharmaceutical Analysis	4	0	0	4
2	PH9102	Pharmaceutical Technology	3	1	0	4
3	PH9103	Dosage Form Design	4	0	0	4
4	PH9104	Biopharmaceutics	4	0	0	4
5	PH9105	Controlled Drug Delivery-Concepts and Advances	3	1	0	4
Practical						
6	PH9106	Modern Methods of Pharmaceutical Analysis Laboratory	0	0	6	3
7	PH9107	Industrial Pharmacy Laboratory	0	0	6	3

SEMESTER II

S.No.	Subject Code	Subject	L	T	P	C
Theory						
1	PH9151	Validation and Regulatory Affairs in Pharmaceutical Industries	3	1	0	4
2	PH9152	Design and Development of Novel Drug Delivery System	3	1	0	4
3	PH9153	Pharmacokinetics	4	0	0	4
4	PH9154	Pharmaceutical Production Planning and Management	3	0	0	3
5	PH9155	Modern Pharmaceutics	4	0	0	4
Practical						
6	PH9156	Novel Drug Delivery Systems Laboratory	0	0	6	3
7	PH9157	Biopharmaceutics and Pharmacokinetics Laboratory	0	0	6	3

SEMESTER III

S.No.	Subject Code	Subject	L	T	P	C
1	PH9201	Dissertation Evaluation and viva voce (Phase I)	0	0	24	12

SEMESTER IV

S.No.	Subject Code	Subject	L	T	P	C
1	PH9251	Dissertation Evaluation and viva voce (Phase II)	0	0	24	12

ANNA UNIVERSITY TIRUCHIRAPPALLI

Tiruchirappalli – 620 024

Regulations 2008

Syllabus

MASTER OF PHARMACY - PHARMACEUTICS

PA9101 – MODERN METHODS OF PHARMACEUTICAL ANALYSIS

L	T	P	C
4	0	0	4

UNIT I INFRA RED SPECTROSCOPY 12

Molecular spectra – Origin of IR spectra – Harmonic oscillator model – Electronic band spectra – Pre dissociation spectra – Vibrations coupling – Instrumentation – Fourier transform spectrometer – Dispersive instruments – Non dispersive instruments – Mid infra red absorption spectrometry – Factors influencing vibrational frequencies – Interpretation of spectral regions in IR – Environmental effects – Molecular shapes and applications of IR.

UNIT II NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY 12

Theory of NMR – Electromagnetism – Diamagnetism – Paramagnetism – Magnetic properties of nuclei and the spin number I – Chemical shift – Shielding and deshielding – Chemical shift regions for different nuclei and substituents – Interpretation of spectra using chemical shift – Spin-Spin coupling and interpretation of spectra – Decoupling – One-dimensional and Two-dimensional NMR spectroscopy – Comparison between one-dimensional and two-dimensional NMR – COSY, TOCSY, NOESY, ROESY spectroscopy – Nuclear overhauser effect

UNIT III MASS SPECTROMETRY 12

Principles – Reactions inside the mass spectrometer – Resolution – Principle of measuring of ion currents – Electron impact – Chemical ionisation – Instrumentation and ionization methods (FAB, ESI, MALDI, FID, etc) – Plasma desorption mass spectrometry – Vacuum system – Mass spectrum – Fragmentation – Rules for predicting prominent peaks in mass spectrum – Rearrangements – Mass spectrometers in the structural elucidation of small and macromolecules.

UNIT IV X RAY AND ELECTRON SPECTROSCOPY 12

X-ray diffraction – Bragg's law – Diffraction of X-rays – Production and detection of X-rays – Sample preparation – Identification of powder diffraction patterns – Quantitative analysis – Principle – Instrumentation and applications of XRD, SEM, TEM.

UNIT V THERMAL AND IMMUNOCHEMICAL ANALYSIS 12

Theory – Instrumentation and applications of TGA, DTA and DSC – Immunoelectrophoresis – Immunoprecipitation – ELISA – Radioimmunoassays

Total: 60

TEXT BOOKS

1. Holler, J.F. and Nieman, T.A., "Principles of Instrumental Analysis", 5th Edition, Harcourt Publishers, 2001.
2. Chatwal.G.R. and Anand, S. K., "Instrumental Methods of Chemical Analysis", Himalaya Publishing House, 2005.

REFERENCES

1. Brown, D.W., Floyd, A.J. and Sainsbury, M., "Organic Spectroscopy", John Wiley and Sons, 1988.
2. Oharnesian, L. and Streeter, A J., "Handbook of Pharmaceutical Analysis", Marcel Dekker Inc., 2002.
3. Willard, H.H., Merritt. L.L., Dean J.A. and Settle, F.A., "Instrumental Methods of Analysis", 7th Edition, CBS Publishers, 2004.

PH9102 – PHARMACEUTICAL TECHNOLOGY

L T P C
3 1 0 4

UNIT I PREFORMULATION STUDIES 9

Preformulation timings and modes – Preformulation stages – Analytical profiles – Chemical properties – Thermodynamic and physicochemical properties – Pharmaceutical and mechanical properties – Solid state characteristics – Biopharmaceutical properties – Stability – Excipient compatibility – Regulatory requirements for preformulation.

UNIT II COMPACTION AND COMPRESSION 9

Compaction of powders – Process of compression – Measurement of compressional forces – Energy expenditure – Transmission of force – Effect of particle size. Moisture content, lubrication on strength of tablets.

UNIT III KINETIC PRINCIPLES AND STABILITY TESTING 9

Chemical degradation of pharmaceutical products – Physical factors influencing chemical degradations – Temperature, moisture, light and radiation – Factors influencing and methods of reducing chemical degradation – Physical degradation of pharmaceutical products – Methods for detecting degradation – Effect of packaging on stability of dosage forms – Estimation of shelf-life of drug products – Evaluation of stability of dosage forms as per ICH guidelines.

UNIT IV OPTIMIZATION 9

Concept of optimization – Optimization parameters – Classic optimization – Statistical design – Optimization methods – Evolutionary operations – Simplex method – Lagrangian method – Search methods

UNIT V PELLETIZATION TECHNOLOGY 9

Rationale for pelletization – Pelletization equipments – Coating pan – Fluidized equipment – Extrusion and spheronizing equipment – Evaluation of pellets.

L: 45 T:15 Total: 60

TEXT BOOKS

1. Liberman, H. A., Lachman, L. and Schwartz, J. B., “Pharmaceutical Dosage Form: Tablets”, 2nd Edition, Volume II, Marcel Dekker, 1999.
2. Banker, G. S. and Rhodes, C.T., “Modern Pharmaceutics”, 4th Edition, Marcel Dekker, CBS Publishers and Distributors, 2002.

REFERENCES

1. Carstenson, J. T. and Rhodes, C.T., “Drug Stability - Principles and Practices” 3rd Edition, Marcel Dekker, CBS Publishers and Distributors, 2000.
2. Lewis, G.A., Mathiea, D. and Phan-Tan-Luu, R., “Pharmaceutical Experimental Design”, Marcel Dekker Inc., 1999.
3. Yoshioka, S., and Stella, V. J., “Stability of Drugs and Dosage Forms”, Springer (India) Private Ltd., 2006.

PH9103 – DOSAGE FORM DESIGN

L T P C
4 0 0 4

UNIT I SOLID DOSAGE FORMS 12

Tablet product design – Compressed tablets – Granulation – Properties – Formulation and design – Manufacture and its problems – Prolonged released tablets – Direct compression – Evaluation of tablets – Tablet coating techniques and equipments – Capsules – Manufacturing equipment and machinery used in capsule technology – Formulation and evaluation of hard gelatin capsules and soft gelatin capsules – Microencapsulation.

UNIT II LIQUID DOSAGE FORMS 12

Pharmaceutical suspension – Stabilization – Formulation– Pharmaceutical emulsion and microemulsion – Characteristics – Formulation components – Processing of emulsion – Emulsion stability – Parental emulsions – Characteristics – Emulsion manufacture – Properties – Stability and evaluation – Parental suspensions – Formulation – Manufacturing considerations – Stability and evaluation – Recent applications of IV suspensions IV emulsions .

UNIT III PARENTRALS 12

Small volume parenterals – Stages in the processing – Manufacture – Packing – Sealing – Labeling – Final product testing– Large volume parenterals – Properties of fluids – Raw materials – Batch mixing – Filtration – Cleaning process equipment – Containers and closures – Filling – Sealing – Labeling – Final product testing – Powders for reconstitution.

UNIT IV AEROSOLS 12

Characteristics of aerosol systems – Properties – Physio- chemical aspects of aerosol systems – Raw materials – Containers – Formulation – Manufacturing – Evaluation of aerosols – Radioactive aerosols – Parental aerosols.

UNIT V RADIO PHARMACEUTICALS 12

Basics of radio pharmacy – Dosage form formulations – Diagnostic and therapeutic uses – Production – Quality assurance – Storage – Disposal of radio pharmaceuticals – Safety and hazards.

Total: 60

TEXT BOOKS

1. Lachman, L. and Lieberman, H. A., “The Theory and Practice of Industrial Pharmacy”, 3rd Edition, Varghese Publishing house, 1986.
2. Ruzer, L.S. and Harley, N.H., “Aerosols Handbook – Measurement, Dosimetry and Health effects”, CRC Press, 2005.

REFERENCES

1. Kenneth, E. A., Lieberman, H. A. and Lachman, L., “Pharmaceutical Dosage Forms: Disperse Systems, Parental Medications, Tablets”, 2nd Edition, Vol II, Marcel Dekker Inc., 1993.
2. Kowalsky, R. J., Falen, S. and Kowalsky, R., “Radiopharmaceuticals in Nuclear Pharmacy and Nuclear Medicine”, 2nd Edition, CRC Press, 2004.
3. Nunn, A.D., “Radiopharmaceuticals: Chemistry and Pharmacology”, Marcel Dekker Inc., CRC Press, 1992.

PH9104 – BIOPHARMACEUTICS

L T P C
4 0 0 4

UNIT I ABSORPTION OF DRUGS 12

Structure of cell membrane – Gastrointestinal absorption of drugs – Mechanisms of drug absorption – Biological, physiological, physicochemical and pharmaceutical factors affecting drug absorption – Absorption of drugs from non-per oral routes – Methods of determining absorption – In-vitro, In-situ and In-vivo methods.

UNIT II DRUG DISTRIBUTION 12

Factors affecting drug distribution – Volume of distribution – Protein binding – Factors affecting, significance and kinetics of protein binding.

UNIT III BIOTRANSFORMATION OF DRUGS 12

Phase I – Oxidative, reductive and hydrolytic reactions – Phase II reactions – Conjugation – Factors affecting biotransformation.

UNIT IV EXCRETION OF DRUGS AND PRODRUGS 12

Renal and non-renal excretion – Concept of clearance – Renal clearance – Organ clearance and hepatic clearance – Prodrugs – Pharmaceutical application – Pharmacokinetic application – Limitations of prodrugs.

UNIT V BIOAVAILABILITY AND BIOEQUIVALENCE 12

Objectives – Considerations in bioavailability studies – Concept of equivalents – Measurement of bioavailability – Determination of the rate of absorption – Bioequivalence and its importance – Bioequivalence studies.

Total: 60

TEXT BOOKS

1. Welling, P.G. and Francis, L.S.Tse., “Pharmacokinetics”, 2nd Edition, CBS Publishers and Distributors, 1995.
2. Brahmkar, D.M. and Jaiswal, S.B., “Biopharmaceutics and Pharmacokinetics”, 1st Edition, Vallabh Prakasan, 2005.

REFERENCES

1. Gibaldi, M., “Biopharmaceutics and Clinical Pharmacokinetics”, 4th Edition, Pharma Book Syndicate, 2005.
2. Shargel, L., Wu-Pong, S. and Yu, B.C.A., “Applied Biopharmaceutics and Pharmacokinetics” 5th Edition, McGraw-Hill, 2004.
3. Notari, R.E., “Biopharmaceutics and Clinical Pharmacokinetics - An Introduction”, 4th Edition, Marcel Dekker Inc, CBS Publishers and Distributors, 1987.

PH9105 – CONTROLLED DRUG DELIVERY - CONCEPTS AND ADVANCES

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3 1 0 4

UNIT I FUNDAMENTALS OF CONTROLLED RELEASE DRUG DELIVERY 9

Fundamentals and rationale of sustained / controlled drug delivery – Factors influencing the design and performance of sustained / controlled release products – Regulatory considerations in controlled drug delivery.

UNIT II POLYMERS USED IN CONTROLLED DRUG DELIVERY 9

Polymer – Classification – Applications for polymers in formulation of controlled drug delivery system – Biodegradable and natural polymers.

UNIT III CONTROLLED RELEASE ORAL DRUG DELIVERY 9

Design and development of oral controlled release drug administration – Dissolution controlled – Diffusion controlled – Reservoir devices – Matrix devices – Membrane permeation controlled – Osmotic pressure controlled – Gel diffusion controlled – pH controlled – Ion-exchange controlled delivery systems.

UNIT IV GASTRORETENTIVE AND COLON SPECIFIC DRUG DELIVERY 9

Gastric emptying – Approaches to increase gastric retention – Factors affecting gastric retention – Floating drug delivery system – Altered density dosage forms – Factors governing the colon drug delivery – Targeting approaches to colon – Formulations for colon specific drug delivery – Preclinical evaluation and animal models for colon specific drug delivery systems.

UNIT V PARENTRAL CONTROLLED RELEASE DRUG DELIVERY 9

Injectable controlled release formulations – Long acting penicillin preparations – Long acting insulin preparations – Long acting steroid preparations – Long acting contraceptive preparations – Approaches and applications of implantable drug delivery systems.

L: 45 T:15 Total: 60

TEXT BOOKS

1. Banker, G.S. and Rhodes, C.T., “Modern Pharmaceutics”, 4th Edition, Informa Health Care, 2002.
2. Chien, Y.W., “Novel Drug Delivery System”, 2nd Edition, Informa Health Care, 1992.

REFERENCES

1. Robinson, J.R. and Lee, V.H.L., “Controlled Drug Delivery System – Fundamentals and Applications”, 2nd Edition, Marcel Dekker Inc., 1987.
2. Vyas, S.P., and Khar, R.K., “Controlled Drug Delivery”, 1st Edition, Vallabh Prakashan, 2002.
3. Gennaro, A R., “Remington: The Science and Practice of Pharmacy”, 21st Edition, Vol I and II, Lippincott Williams and Wilkins, 2005.

PH9106 – MODERN METHODS OF PHARMACEUTICAL ANALYSIS LABORATORY

L T P C
0 0 6 3

1. Calibration of UV spectrometer through absorbance and wavelength checks.
2. Determination of effects of slit width and scanning speed on the UV absorption spectrum of a given drug.
3. Assay of caffeine and sodium benzoate injection by simultaneous equation method and absorbance.
4. Acquisition of $^1\text{H-NMR}$ spectrum of simple organic molecules and assignments of the signals to the structures.
5. Recording of IR absorption spectrum of a drug using KBR discs thin film techniques.
6. Determination of paracetamol in plasma using reversed phase HPLC.
7. Determination of amount of phenobarbitone in phenobarbitone tablets.
8. Identification of drug molecules by TLC.
9. Validation of analytical methods.
10. Effect of pH on absorbance spectrum of phenolic compounds (Paracetamol).
11. Determination of drug concentration in sample by derivative spectroscopy.

Total: 90

PH9107 – INDUSTRIAL PHARMACY LABORATORY

L	T	P	C
0	0	6	3

1. Preparation and evaluation of sodium sulphate effervescent granules.
2. Preparation and evaluation of ferrous sulphate granules.
3. Determination of surface area of stearic acid by adsorption method.
4. Preparation of benzyl benzoate application and determination of its globule size.
5. Determination of rate of drug release from various ointment bases.
6. Preparation of calcium gluconate and dextrose injections.
7. Quality control tests for coated and uncoated tablets.
8. Quality control tests for capsules.
9. Hydrolytic resistance of glass containers.
10. Determination of preformulation parameters of two drugs.
11. Formulation and evaluation of gels.
12. Formulation and evaluation of solid dispersions.

Total: 90

PH9151 – VALIDATION AND REGULATORY AFFAIRS IN PHARMACEUTICAL INDUSTRIES

L T P C
3 1 0 4

UNIT I US-FDA REGULATORY AFFAIRS 9

Application and approval process of US FDA for investigational new drug– New drug – Hatch Waxman amendment – Abbreviated new drug application for generic market – Types– Data presentation – Verification and grant by FDA – Common technical documentation– Drug master file– Type – Filing process – Benefits – New product exclusivity – Patent term restoration – 180 day exclusivity and orange book listings – Federal register.

UNIT II ICH GUIDELINES 9

Stability testing of new drug substances and products [Q1A (R2)] – Stability testing – Photo stability testing of new drug substances and products [Q1B] – Bracketing and matrixing designs for stability testing of new drug substances and products [Q1D] – Evaluation of stability data [Q1E] – Impurities in new drug substances [Q3A(R)] – Impurities in new drug products [Q3B(R)] – Impurities guideline for residual solvents [Q3C].

UNIT III QUALITY AUDIT AND SELF INSPECTIONS 9

SOPs – Documentation – Master formula records – Batch manufacturing records – Contract licenses – Complaints recalls.

UNIT IV VALIDATION 9

Concepts – Process validation – Benefits – Protocol – Equipment validation – Nonsterile and sterile validation – Analytical method validation – Validation of personnel – Water supply system – Electronic data – Cleaning validation.

UNIT V GOOD LABORATORY PRACTICES 9

US – FDA guidelines for GLP for laboratories conducting non clinical animal testing – Good clinical practice – Basic rules on how to carry out a clinical investigation of drugs in Phase I, II, III and IV clinical trials – Subjects of clinical investigation – Documentation of studies – Ethical aspects of clinical investigations of drugs.

L: 45 T:15 Total: 60

TEXT BOOKS

1. Pisano, J.R. and Mantus, D., “FDA Regulatory Affairs”, CRC Press, 2003.
2. Loftus, B.T. and Nash, R.A., “Pharmaceutical Process Validation”, 3rd Edition, Drugs and Pharm Sci. Series, Marcel Dekker Inc., 2003.

REFERENCES

1. Willig, H., Tuckeman, M.M. and Hitchings, W.S., “Good Manufacturing Practices for Pharmaceuticals”, 5th Edition, Drugs and Pharm. Sci. Series, Marcel Dekker Inc., 2000.
2. Banker, G.S and Rhodes, C.T., “Modern Pharmaceutics”, 4th Edition, Marcel Dekker Inc., CBS Publishers and Distributors, 2002.
3. Bleidt, B. and Montagne, M., “Clinical Research in Pharmaceutical Development”, 1st Edition, Marcel Dekker Inc., 1996.

PH9152 – DESIGN AND DEVELOPMENT OF NOVEL DRUG DELIVERY SYSTEM

L	T	P	C
3	1	0	4

UNIT I PROTEIN AND PEPTIDE DRUG DELIVERY SYSTEMS 9

Needs – Advantages – Routes of delivery – Applications – Current scenario – Penetration barriers – Types of barriers – Means to overcome penetration barriers – Metabolic clearance – Systemic clearance of peptide and protein drug – Approaches to reduce systemic clearance.

UNIT II MUCO-ADHESIVE DRUG DELIVERY SYSTEMS 9

Introduction – Buccal drug delivery system – Concepts – Advantages and disadvantages – Structure of oral mucosa – Transmucosal permeability – Mucosal membrane modules – Permeability enhancers – In vitro and in vivo methods for buccal absorption – Buccal strips – Nasal drug delivery systems – Physiology of nose – Fundamentals of nasal absorption – In vitro and in vivo methods for determination of nasal absorption – Applications of nasal drug delivery system – Pulmonary drug delivery system and its applications.

UNIT III TARGETTED DRUG DELIVERY SYSTEMS 9

Formulation – Characterization – Applications of microspheres – Magnetic microspheres – Nanoparticles – Liposomes – Niosomes – Resealed erythrocytes.

UNIT IV ANTIBODY THERAPEUTICS 9

Engineering of therapeutic antibodies to minimize immunogenicity and optimize function – Formulation and delivery issues for monoclonal antibody therapeutics – Current and future issues in the manufacturing and development of monoclonal antibodies.

UNIT V NOVEL TECHNOLOGY 9

Nanotubes – Types – Synthesis, purification and applications – Application of micro and nano electromechanical devices in drug delivery.

L: 45 T: 15 Total: 60

TEXT BOOKS

1. Jain, N.K., “Advances in Controlled and Novel Drug Delivery”, 1st Edition, CBS Publishers and Distributors, 2001.
2. Vyas, S.P. and Khar, R.K., “Targeted and Controlled Drug Delivery”, 1st Edition, CBS Publishers, 2002.

REFERENCES

1. Chien, Y.W., “Novel Drug Delivery Systems”, 2nd Edition, Marcel Dekker Inc., 1991.
2. Praveen, T., “Drug Delivery Devices”, 2nd Edition, Marcel Dekker Inc., 1998.
3. Mathiowitz, E., “Encyclopedia of Controlled Drug Delivery”, 1st Edition, Vol I and II, Wiley Interscience Publication, 1999.

PH9153 – PHARMACOKINETICS

L T P C
4 0 0 4

UNIT I PHARMACOKINETICS 12

Basic considerations – Pharmacokinetic models – Compartment modeling – One compartment model – IV bolus, IV infusion and extra vascular – Two compartment model – IV bolus, IV infusion and extra-vascular – Three compartment model in brief.

UNIT II NONLINEAR AND NONCOMPARTMENTAL PHARMACOKINETICS 12

Cause of non-linearity – Michaelies-Menten equation – Estimation of K_m and V_{max} . – Clearance – Half life – Volume of distribution – Drug concentration at steady state – Area under curve – Noncompartmental pharmacokinetics – Statistical moment theory – Estimation of bioavailability, clearance, half-life, absorption kinetics, volume of distribution and steady state concentration.

UNIT III DOSAGE REGIMEN 12

Multiple dosing with respect to IV and oral route – Concept of loading dose – Maintenance dose – Accumulation index – Adjustment of drugs dosage (Digoxin, gentamycin and anticonvulsants) in renal and hepatic impairment – Individualization of therapy – Therapeutic drug monitoring.

UNIT IV PHARMACOKINETIC VARIABILITY 12

Body weight, size, obesity, sex, pregnancy and genetic factors – Neonates, infants and children – Elderly patients – Drug metabolism – Plasma protein binding and renal excretion in new borns and children – Drug elimination in aged.

UNIT V CLINICAL DRUG RESEARCH 12

Planning, coordinating and monitoring of clinical trials – Protocol – Case report forms and patient consent – Patient outcomes and drug usefulness.

Total: 60

TEXT BOOKS

1. Gibaldi, M., “Biopharmaceutics and Clinical Pharmacokinetics”, 4th Edition, Pharma Book Syndicate, 2005.
2. Brahmankar, D.M. and Jaiswal. S.B., “Biopharmaceutics and Pharmacokinetics”, 1st Edition, Vallabh Prakasan, 1995.

REFERENCES

1. Shargel, L., Wu-Pong, S. and Yu, B.C.A., “Applied Biopharmaceutics and Pharmacokinetics” 5th Edition, McGraw-Hill, 2004.
2. Bleidt, B. and Montagne, M., “Clinical Research in Pharmaceutical Development”, 1st Edition, Marcel Dekker, 1996.
3. Gibaldi. M. and Perrier, D., “Pharmacokinetics”, 2nd Edition, Marcel Dekker Inc, 1982.

PH9154 – PHARMACEUTICAL PRODUCTION PLANNING AND MANAGEMENT

L T P C
3 0 0 3

UNIT I PILOT PLANT AND SCALE-UP TECHNIQUES 9

Pharmaceutical pilot plant design – Case studies for tablets – Capsules – Aerosols – Liquid orals – Parentrals – Sustained release preparation – Semi solid preparation – Basic requirements – Design of product – Facility – Equipment selection and personnel.

UNIT II PRODUCTION PLANNING, SCHEDULING AND FORECASTING 9

Production planning and inventory control management – Purchasing – Vendor development – Machine – Human resources – Excise assessment of production – Rate changes – Costing of products and cost controls.

UNIT III MATERIAL MANAGEMENT AND HUMAN RESOURCE DEVELOPMENT 9

Materials – Quality and quantity – Value analysis – Purchasing – Centralized and decentralized – Vendor development – Buying techniques – Purchasing cycle and procedures – Stores management – Salvaging and disposal of scrap surplus – Selection of material handling system – Maintenance material handling equipments – Unit-load – Pelletization and containerization – Types of material handling system – Human resource development – Personnel training – Job specification – Job enlargement and enrichment – Blue and white collar jobs – Labor welfare.

UNIT IV FORMULATION PRODUCTION MANAGEMENT 9

Plant site selection and layout – Material handling for various pharmaceutical products – Service facilities – Preventive maintenance in pharmaceutical companies – Group and individual replacement.

UNIT V SAFETY AND EFFLUENT TESTING 9

Industrial hazards due to fire – Accident – Mechanical – Electrical equipment – Monitoring and preventive system – Safety measures including insurance – Effluent treatment and waste management.

Total: 45

TEXT BOOKS

1. Lachman, L. and Lieberman, H. A., “The Theory and Practice of Industrial Pharmacy”, 3rd Edition, Varghese Publishing house, 1986.
2. Subramaniam, C.V.S., “Textbook of Pharmaceutical Production Management”, Vallabh Prakashan, 2005.

REFERENCES

1. Sharma, P.P., “How to Practice GMPs” 2nd Edition, Vandana Publications, 2004.
2. Evans, J.R., “Applied Production and Operations Management”, 1st Edition, West Publishing Company, 1992.
3. Drucker, P.F., “Management: Tasks, Responsibilities and Practices”, 1st Edition, Allied Publication, 1993.

PH9155 – MODERN PHARMACEUTICS

L	T	P	C
4	0	0	4

UNIT I TRANSDERMAL DRUG DELIVERY SYSTEMS 12

Permeation through skin – Factors affecting permeation – Basic components of TDDS – Formulation approaches used in development of TDDS and their evaluation – Permeation enhancers.

UNIT II OCULAR DRUG DELIVERY SYSTEMS 12

Physiology of eye formulation – Absorption of drugs in eye – Ocular controlled drug delivery systems – Ocular drug delivery devices – Particulate and vesicular systems for ocular delivery.

UNIT III PACKAGING OF PHARMACEUTICAL DOSAGE FORMS 12

Types of containers – Glass – Elastomeric closures – Plastics – Metal – Paper and board – Special packaging – Analysis and control of packaging materials – Blister and strip packaging – Packaging related contents in the official compendia.

UNIT IV DISSOLUTION 12

Importance – Biological classification system – Biological disposition classification system – Design of apparatus – In-vitro and In-vivo correlation.

UNIT V INTELLECTUAL PROPERTY RIGHTS 12

Definitions – Need for patenting – Types of patents procedures for applying patent – Types of patents – Infringement of patents – Patents act 1970 – The Patent Rules 2003 as amended by The Patents (Amendment) Rule 2006 – GATT – TRIPS.

Total: 60

TEXT BOOKS

1. Vyas, S.P. and Khar, R.K., “Controlled Drug Delivery- Concepts and Advances”, 1st Edition, Vallabh Prakashan, 2002.
2. Gennaro, A R., “Remington: The Science and Practice of Pharmacy”, 21st Edition, Vol I and II, Lippincott Williams and Wilkins, 2005.

REFERENCES

1. Banker, G. S. and Rhodes, C.T., “Modern Pharmaceutics”, 4th Edition, Marcel Dekker, CBS Publishers and Distributors, 2002.
2. Rowe, R., Sheskey. P. and Owen, S., “Handbook of Pharmaceutical Excipients”, 5th Edition, Pharmaceutical Press, McGraw-Hill, 2005.
3. Welling. P.G. and Francis L.S.Tee, “Pharmacokinetics”, 2nd Edition, Marcel Dekker Inc., 2005.

PH9156 – NOVEL DRUG DELIVERY SYSTEM LABORATORY

L T P C
0 0 6 3

1. Preparation and evaluation of niosomes containing ciprofloxacin.
2. Formulation and evaluation of egg albumin microspheres of ciprofloxacin by single emulsion technique.
3. Formulation and evaluation of ofloxacin microcapsules by emulsion solvent evaporation method.
4. Formulation and evaluation of norfloxacin microcapsules through co-acervation phase separation by solvent evaporation method.
5. Formulation and evaluation of paracetamol solid dispersion by fusion method.
6. Formulation and evaluation of indomethacin solid dispersion by melting point solvent technique.
7. Preparation of solid dispersion of aspirin by common solvent evaporation method.
8. Preparation and evaluation of niosomes containing ofloxacin.
9. Preparation and evaluation of paracetamol solid dispersion by melting solvent technique.
10. Preparation and evaluation of solid dispersion by common solvent method.
11. Preparation and evaluation of ofloxacin microspheres by emulsion solvent technique.

Total: 90

PH9157 – BIOPHARMACEUTICS AND PHARMACOKINETICS LABORATORY

L	T	P	C
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1. Determination of rate constant and half life of pseudo first order reaction.
2. Determination of partition coefficient and effect of pH on the partition coefficient of drugs.
3. Dissolution study of enteric coated tablets.
4. Determination of protein binding of various drugs.
5. Effect of protein concentration on invitro drug release of drugs.
6. Comparison of in vitro release profile of marketed conventional tablets.
7. Comparison of in vitro release of marketed sustained release tablets.
8. Pharmacokinetic profile of extra vascular administration of drugs using plasma data.
9. Determination of pharmacokinetic parameters of drugs administered through extra vascular route using urinary excretion data.
10. Determination of pharmacokinetic parameters of drugs administered through extra vascular route using salivary excretion data.
11. Release kinetics of delayed release tablets.

Total: 90