

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

S.No.	Subject Code	Subject	L	T	P	C
Theory						
1	PA9101	Modern Methods of Pharmaceutical Analysis	4	0	0	4
2	PA9102	Pharmaceutical Production Management	3	0	0	3
3	PA9103	Regulatory affairs in Pharmaceutical Industries	3	1	0	4
4	PA9104	Quality control of Pharmaceuticals I	4	0	0	4
5	PH9153	Pharmacokinetics	4	0	0	4
Practical						
6	PA 9106	Modern Methods of Pharmaceutical Analysis Laboratory	0	0	6	3
7	PA 9107	Spectral Workshop Laboratory	0	0	6	3

SEMESTER II

S.No.	Subject Code	Subject	L	T	P	C
Theory						
1	PA9151	Analytical Medicinal Chemistry	4	0	0	4
2	PA9152	Development and Validation of Analytical Methods	3	1	0	4
3	PA9153	Computing Techniques in Pharmaceutical Analysis	3	0	0	3
4	PA9154	Pharmaceutical Quality Assurance	4	0	0	4
5	PA9155	Quality Control of Pharmaceuticals II	4	0	0	4
Practical						
6	PA9156	Analytical Medicinal Chemistry Laboratory	0	0	6	3
7	PA9157	In-process Quality Control Laboratory	0	0	6	3

SEMESTER III

S.No.	Subject Code	Subject	L	T	P	C
1	PA9201	Dissertation Evaluation and viva voce (Phase I)	0	0	24	12

SEMESTER IV

S.No.	Subject Code	Subject	L	T	P	C
1	PA9251	Dissertation Evaluation and viva voce (Phase II)	0	0	24	12

ANNA UNIVERSITY TIRUCHIRAPPALLI

Tiruchirappalli – 620 024

Regulations 2008

Syllabus

MASTER OF PHARMACY - PHARMACEUTICAL ANALYSIS

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.

PA9102 – PHARMACEUTICAL PRODUCTION MANAGEMENT

L	T	P	C
3	0	0	3

UNIT I QUALITY MANAGEMENT 9

Concept of TQM – ISO-9000 – Salient features – ISO 14000 and 18000 (EHS) – Human resource management – Organization and personnel – Responsibilities – Training – Hygiene and records.

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

TEXTBOOKS

1. Vidyasagar, G., “Pharmaceutical Industrial Management”, 3rd Edition, Varghese Publications, 2001.
2. Subramaniam, C.V.S., “Textbook of Pharmaceutical Production Management”, Vallabh Prakashan, 2005.

REFERENCES

1. Lachman, L. and Liberman, H.A., “The Theory and Practice of Industrial Pharmacy”, 3rd Edition, Varghese Publications, 1986.
2. Evans, J.R., Anderson, D.R., Sweeny, D.J. and Williams, T.A., “Applied Production and Operations Management”, 3rd Edition, West Publishing Company Ltd, 1990
3. Drucker, P.F., “Management (Task, Responsibility and Practices)”, Allied Publication, 1993.

PA9103 – 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 (IND) - New Drug (NDA) – Hatch – Waxman amendment – Abbreviated New Drug Application (ANDA) for generic market – Types of ANDA – Data presentation – Verification and grant by FDA – Common Technical Documentation (CTD) – Drug master File (DMF) – Type – Filing process – Benefits. New product exclusivity – Patent term restoration - 180 day exclusivity and orange book listings – Federal register.

UNIT II EUROPEAN COMMISSION REGULATORY AFFAIRS 9

Procedure for marketing authorization in European commission countries – Mutual recognition – NABL accreditation process – Organization and functioning of ICH – Overview of various ICH guidelines.

UNIT III ICH GUIDELINES 9

Stability testing of new drug substances and products [ICH guidelines Q1A(R2)] – Stability testing – Photo stability testing of new drug substances and products [ICH guidelines Q1B]- Stability testing for new dosage forms [ICH guidelines Q1C] – Bracketing and matrixing designs for stability testing of new drug substances and products [ICH guidelines Q1D] – Evaluation of stability data [ICH guidelines Q1E] – Impurities in new drug substances [ICH guidelines Q3A(R)] – Impurities in new drug products [ICH guidelines Q3B(R)] – Impurities guideline for residual solvents [ICH guidelines Q3C].

UNIT IV GOOD LABORATORY PRACTICES 9

USFDA 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.

UNIT V INTELLECTUAL PROPERTY RIGHTS 9

Introduction – Patent system – Different types of patents – Filing process of application for patent – Infringement of patents – The Patent Act 1970 – The Patent Rules 2003 as amended by The Patents (Amendment) Rule 2006.

L: 45 T: 15 Total: 60

TEXT BOOKS

1. Nash, R.A. and Wachter, A.H., "Pharmaceutical Process Validation", 3rd Edition, Volume 129, Marcel Dekker Inc., 2003.
2. Willig, S. H. and Tuckerman, M.M., "Good Manufacturing Practices for Pharmaceuticals", 2nd Edition, Vol. 16, Marcel Dekker Inc., 1982.

REFERENCES

1. Subbaram, N.R., "What everyone should Know about Patents", 2nd Edition, Pharma Book Syndicate, 2005.
2. Banker, G.S. and Rhodes, C.T., "Modern Pharmaceutics", 4th Edition, Marcel Dekker, CBS Publishers and Distributors, 2002.
3. Sharma, P.P., "How to Practice GMPs", 2nd Edition, Vandana Publications, 2006.

PA9104 – QUALITY CONTROL OF PHARMACEUTICALS I

L	T	P	C
4	0	0	4

UNIT I PREFORMULATION STUDIES 12

Study of physical properties of drug like physical form – Particle size, shape, density, wetting dielectric constant – Partition co-efficient – Solubility – Dissolution crystal form and stability – Compatibility tests and organoleptic property and their effect on formulation – Stability and bioavailability – Study of chemical properties of drugs – Hydrolysis, oxidation, reduction, racemization, polymerization and their influence on formulation and stability of products – Study of pro-drugs in solving problems related to stability bioavailability and elegance of formulations.

UNIT II PERFORMANCE EVALUATION METHODS 12

In vitro dissolution studies for solid dosage forms – In vitro drug dissolution testing models – method interpretation of dissolution data – Bioavailability studies and bioavailability testing protocol and procedures – In vivo methods of evaluation and statistical treatment – In vitro in-vivo correlation (F2 Factor) – Various invitro and in vivo models.

UNIT III STANDARDIZATION OF HERBAL PRODUCTS 12

WHO guide lines of the standardization of herbal raw materials and finished products – Morphological, microscopical, cytomorphological and chemical examinations of raw materials and finished products – Determination of physical and chemical constants such as extractive values, moisture content, alcohol content, volatile oil content, ash values, bitterness values, foreign matters. Physical constants applicable to the lipid containing drugs – Microbial counts – Bioburden – Pharmacopoeial microbial assays – Physicochemical characterization in whole form – Separation and identification of active principles – Excipients and their estimation by different techniques.

UNIT IV PACKAGING TECHNOLOGY 12

Packaging design and specifications – Packaging validation trials – Material of construction, component product validation – Regulatory requirements – Quality control testing and standards – GMP requirements and its deficiencies – Documentation – Sterilization of packaging components – Packaging and filling equipment – Pharmaceutical packaging including sterile filling area – Customer complaints.

UNIT V BIOASSAY OF DRUGS AND BIOLOGICAL STANDARDIZATION 12

Bioassay definition – Merits and demerits of bioassay – Biological standardization – Threshold dose, bracketing – Four point and other assays – Bioassay of acetylcholine, hydroxytryptamine, adrenaline, noradrenaline, sedative agents, oxytocin, digitalis, different hormones, anesthetics, local anesthetics, etc – Microbial assays of antibiotics – Vitamins (Vitamin B₁₂ and Niacin) – Amino acids.

Total: 60

TEXT BOOKS

1. Agrawal, S.S. and Paridhavi, S. M., “Herbal Drug Technology”, Universities Press, 2007.
2. Tripathi, K.D., “Essentials of Medical Pharmacology”, 4 th Edition, Jaypee Brothers Medical Publishers (P) Ltd, 1999.

REFERENCES

1. Brahmkar, D.M. and Jaiswal, S. B., “Biopharmaceutics and Pharmacokinetics”, 1st Edition, Vallabh Prakasan, 2007.
2. Gosh, M.N., “Fundamentals of Experimental Pharmacology”, 2nd Edition, Scientific Book Agency, 1984.
3. Lachman, L. and Liberman, H.A., “The Theory and Practice of Industrial Pharmacy”, 3rd Edition, Varghese Publications, 1986

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 Extravascular – 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 Inc, 1996.
3. Gibaldi. M. and Perrier, D., “Pharmacokinetics”, 2nd Edition, Marcel Dekker Inc., 1982.

**PA9106 – 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 by absorbance.
4. Acquisition of 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. Gas chromatographic determination of the composition of fatty acid in oil.
9. Identification of drug molecules by TLC.
10. Estimation of drugs in biological fluids.
11. Validation of analytical methods.

Total: 90

PA9107 – SPECTRAL WORKSHOP LABORATORY

L T P C
0 0 6 3

1. Interpretation of UV Spectra of some Chemicals and drugs.
2. Interpretation of IR Spectra of some Chemicals and drugs.
3. NMR Interpretation.
4. Determination of Molecular Weight using Mass Spectrometer.
5. Structural elucidation of Organic Molecules.
6. Mass Spectral Fragmentation calculation.
7. IR Data Bank.
8. Mass Data Bank.
9. ELISA Test / LAL Test.
10. Estimation of drugs in biological fluids.

Total: 90

PA9151 – ANALYTICAL MEDICINAL CHEMISTRY

L T P C
4 0 0 4

UNIT I HIGH PRESSURE LIQUID CHROMATOGRAPHY 12

Theory of chromatography – Applications and recent trends in chromatography – High pressure liquid chromatography and high pressure thin layer chromatography – Principle – Instrumentation – Sample preparation – Injection and detection – Method development for reversed – Phase separation – Problems – Column efficiency and selectivity – Applications – LC-MS: Ion source – ESI, APCI – Different techniques – SIM, TIC, Positive mode and negative mode – Applications LC-MSMS.

UNIT II GAS LIQUID CHROMATOGRAPHY WITH MASS SPECTROMETRY 12

Gas chromatography – Liquid chromatography – Mass spectrometry – Basic principle, Instrumentation – Selection of liquid stationary phases – Fragmentation – Application – MALDI- Derivatisation in GC – GC detectors – Evaluation – Branches of GC – Sample preparation – Method development in GC – Sample preparation – Method development in GC – Problems – Applications – GC-MS various types of interfaces, applications.

UNIT III MODERN CHROMATOGRAPHIC TECHNIQUES 12

Planar chromatography – Chiral chromatography – Supercritical fluid chromatography – Affinity chromatography – Bioanalytical chromatography – Ion pair chromatography principle – Instrumentation – Experimental techniques – Detection method – Applications.

UNIT IV ELECTROPHORESIS 12

Factors affecting ionic migration – Effect of temperature – P^H – Ionic strength – Electro-osmosis – Supporting medium – Detection of separated components – Applications of traditional zone electrophoresis – High performance capillary – Applications

UNITV ATOMIC ABSORPTION AND EMISSION SPECTROSCOPY 12

Atomic absorption and emission spectroscopy – Principle – Grotrian diagram – Instrumentation – advantages and disadvantages – Detection limit and sensitivity – Interference – Applications – Basic principle.

Total: 60

TEXT BOOKS

1. Skoog, D.A., “Principles of Instrumental Analysis”, 3rd Edition, Saunders College Publishing, 1985.
2. Willard, H.H., Merritt. L.L., Dean J.A., and Settle, F.A., “Instrumental Methods of Analysis”, 7th Edition, CBS Publishers, 2004.

REFERENCES

1. Chatwal, G.R. and Anand, S. K., “Instrumental Methods of Chemical Analysis”, 5th Edition, Himalaya Publishing House, 2007.
2. Wim Kok ., “Capillary Electrophoresis : Instrumentation and Operation” Vol.51, Stefanie Hoffmann, 2000.
3. Hamilton, R.J., “Introduction to High Performance Liquid Chromatography”, Chapman and Hall, 1978.

PA9152 – DEVELOPMENT AND VALIDATION OF ANALYTICAL METHODS

L	T	P	C
3	1	0	4

UNIT I ERRORS IN ANALYSIS 9

Accuracy (absolute method, comparative method) – Precision – Classification of errors – Estimation of errors – Sources of errors minimization of errors – Normal distribution of errors.

UNIT II CALIBRATION AND STANDARDIZATION 9

Calibration signals – Apparatus – Calibration curves – External standard methods – Internal standard methods – Standard addition methods (applications in HPLC and GLC with calculations) – Linear regression of straight line calibration curves using the regression equation – Sensitivity – Selectivity – Detection limits (application and calculations).

UNIT III SAMPLE COLLECTION AND PREPARATION FOR ANALYSIS 9

Importance of sampling techniques – Sampling techniques – Random, stratified, systematic, cluster, for quality control – Sample preparation – Separating analyte from interferants – Extraction – Automated extraction – Solid phase extraction – Solid phase micro extraction – Super critical fluid extraction and microwave assisted extraction.

UNIT IV HPLC METHOD DEVELOPMENT AND VALIDATION 9

Different types of related substance analysis – Preparation before method validation – Need for validation – Validation of analytical procedures – Methodology – Guidelines of ICH; FDA; USP – Understanding the following concepts in validation – Accuracy – Precision – Specificity – Limit of detection – Limit of quantification – Blind analysis of standard sample – Ruggedness testing – Robustness testing – Equivalency testing – Regulatory guidelines on Bio-analytical method validation.

UNIT V OPTIMIZATION TECHNIQUES 9

Concept of optimization – Optimization parameters – Classical optimization – Statistical designs – Factorial design – Definitions – factor, level, effects – Interactions – Advantages – Performing factorial experiments – Example fractional factorial designs – Composite designs to estimate curvature – Simplex lattice – Sequential optimization.

L: 45 T: 15 Total: 60

TEXT BOOKS

1. Bolton, S. and Bon, C., “Pharmaceutical Statistics – Practical and Clinical Applications”, Vol 135, 4th Edition, Marcel Dekker Inc., 2004.
2. Skoog, D.A., West, D.M. and Holler, F.J., “Fundamentals of Analytical Chemistry”, 7th Edition, Brooks Cole, 1995.

REFERENCES

1. Vogel, I. and Bassett, J., “Vogel’s, Text Book for Quantitative Inorganic Analysis”, 4th Edition, Longman, 1978.
2. Nash, R.A. and Wachter, A.H., “Pharmaceutical Process Validation”, 3rd Edition, Volume 129, Marcel Dekker Inc., 2003.
3. ICH guidelines on validation, www.ich.org

PA9153 – COMPUTING TECHNIQUES IN PHARMACEUTICAL ANALYSIS

L	T	P	C
3	0	0	3

UNIT I **PROBABILITY** **9**

The binomial and nominal distributions – Their significance – Statistical interference – Introduction – Parameter estimation – Hypothesis testing – T tests-F tests, ANOVA, chi squared test.

UNIT II **REGRESSION CORRELATION** **9**

Introduction – Least squares curve fitting – The co-efficient of determination – Confidence intervals in linear regression – Correlation analysis – Simple non linear regression – Higher dimensional least square fit-analysis of variance.

UNIT III **CONTROL CHARTS** **9**

Constructing control charts between batch variations as a measure of variability – Quality control charts in research and development – Quality control charts for proportions.

UNIT IV **DATA HANDLING** **9**

Spread sheet applications – Electronic signatures – E-filing, 21CFR, Part No.11 – Common Technical Documentation.

UNIT V **INTRODUCTION TO DATA STRUCTURE** **9**

Like Queues – List – Trees – Binary trees algorithms – Flow char – Structured Systems – Analysis and development – Ingress-SQL – Gateways etc – Statistics – Methodologies.

Total: 45

TEXT BOOKS

1. Volk, W., “Applied Statistics for Engineers”, 2nd Edition, McGraw-Hill Book Company, Inc, 1958
2. Gupta, S.C. and Kapoor, V.K., “Fundamentals of Mathematical Statistics”, 11th Edition, Sultan Chand and Sons, 2003.

REFERENCES

1. Chambers, D. S. and Wheeler, D.J., “Understanding Statistical Process Control”, 2nd Edition, Donald, 1992.
2. Ott, E.R. and Schilling, E. G., “Process Quality Control: Troubleshooting and Interpretation of Data”, 2nd Edition, McGraw-Hill,1990.
3. Taylor, A.G., ‘SQL For Dummies’ 6th Edition, For Dummies, 2006

PA9154 – PHARMACEUTICAL QUALITY ASSURANCE

L	T	P	C
4	0	0	4

UNIT I PROCESS VALIDATION 12

Design – Development and process validation methods – Protocols – Methodology and interpretation of data for pharmaceutical operations involved in the production of pharmaceutical products with special reference to tablets, suspensions – Validation of process like mixing, granulation, drying, compression filling and water process system.

UNIT II EQUIPMENT VALIDATION 12

Installation qualification and operational qualification for sterilization equipments like autoclave – Oven and membrane filter – Validation of electronic data – Processing – Software validation methodology.

UNIT III CLEANING VALIDATION 12

Analytical method validation requirements and validation of effective cleaning – Vendor validation – Vendor audit – Sample testing and trend analysis – Validation of service – Training – Maintenance and packing.

UNIT IV SCHEDULE M 12

Good manufacturing practices for premises and materials – Self inspection – Quality audit – Master formula records – Batch manufacturing records – Contract licenses – Standard operating procedure – Product recall – Requirements of plant and equipments.

UNIT V SPECIFIC REQUIREMENTS IN SCHEDULE M 12

Specific requirements for manufacturing of sterile preparations (SVP, LVP and Ophthalmic preparations) – Non-sterile preparations (Tablets, Capsules, Syrups, Elixirs, Emulsions, Suspensions, Creams, Ointments, Pastes, Lotions, Dusting powders, Identical products and Meter-Dose – Inhalers – Manufacturing of bulk drugs.

Total: 60

TEXT BOOKS

1. Weinberg, S., “Good Laboratory Practice Regulations”, 2nd Edition, Marcel Dekker Inc., 1995.
2. Swarbrick, J., Boylan, J. C, “Encyclopedia of Pharmaceutical Technology”, Vol – I to III, Marcel Dekker Inc., 2002.

REFERENCES

1. Ira, R., Berry, J.R and Nash, R.A., “Pharmaceutical Process Validation”, Vol – 57, Marcel Dekker Inc.,, 1993.
2. Will, S.H and Stoker, J.R., “Good Manufacturing Practices for Pharmaceutics”, Marcel Dekker.
3. Anonymous, “Quality Assurance of Pharmaceuticals - A Compendium of Guidelines and Related Materials.”, Vol- II, 2nd edition, World Health Organisation, 2007.

PA9155 – QUALITY CONTROL OF PHARMACEUTICALS II

L	T	P	C
4	0	0	4

UNIT I KINETIC PRINCIPLES AND STABILITY TESTING 12

Order of reaction – Influence of pH – Temperature – Acid - base catalysis – Effect of ionic strength on degradation – Complex reactions – Amide hydrolysis – Ring alteration – Oxidation – Reduction – Chemical and physical stability of dosage forms – Influence of packaging components on dosage form stability – Evaluation of stability of dosage forms as per ICH guidelines.

UNIT II IN PROCESS QUALITY CONTROL 12

In process control during component manufacture – Solid dosage forms – Liquid dosage forms – Semi solid dosage forms – Inhalations – Sterile solutions – Novel drug delivery systems – Various IP, BP, USP Methods.

UNIT III PROCESS ANALYTICAL TECHNOLOGY (PAT) 12

Implementation of process analytical technologies in the industrial settings – Generalized process analytical works – PAT applications – Chemometrics – Online applications in pharmaceutical industries.

UNIT IV COMPARATIVE STUDY OF ANALYTICAL METHODS OF DRUGS 12

Streptomycin – Amoxycillin – Kanamycin – Gentamycin – Norfloxacin – Sulphacetamide – Sulphaguanidine – Paracetamol – Ibuprofen.

UNIT V CONTAMINATION OF BIO DRUGS 12

Classification of contaminants – Need for their detection – Detection and estimation of arsenic and heavy metals – Cadmium and lead – Determination of pesticide residues and microorganisms – Introduction to process analytical technology.

Total: 60

TEXT BOOKS

1. Brewer, R. F., “Design of Experiments for Process Improvement and Quality Assurance”, Narosa Publishing House, 1996.
2. Sethi, P.D., “Quantitative Analysis of Drugs in Pharmaceutical Formulations”, 3rd Edition, C.B.S. Publishers and Distributors, 2003.

REFERENCES

1. Evans, W.C., “Trease and Evans: Pharmacognosy”, Baillire Tinda, 1996.
2. Bakeev, K.A., “Process Analytical Technology”, Blackwell Publishers, 2006.
3. Lachman, L. and Liberman, H.A., “The Theory and Practice of Industrial Pharmacy”, 3rd Edition, Varghese Publications, 1986.

PA9156 – ANALYTICAL MEDICINAL CHEMISTRY LABORATORY

L T P C
0 0 6 3

1. HPLC method developments
2. Validation of HPLC methods
3. Validation of an analytical method
4. Microbiological limit test of starch, acacia and antacid preparation
5. To study the pharmacokinetics of suitable drug after oral administration
6. Dissolution and bioequivalence studies of different brands of tablets
7. Studies on salivary excretion of drugs such as paracetamol
8. Effect of excipients such as binders or diluents on the dissolution and bioavailability of drugs
9. Study of suitable drug using one compartment model

Total: 90

PA9157 – IN-PROCESS QUALITY CONTROL LABORATORY

L T P C
0 0 6 3

1. In Process Quality Control Tests for Suspensions as per IP, BP and USP methods
2. Process Quality Control Tests for Tablets as per IP, BP and USP methods
3. Process Quality Control Tests for Capsules as per IP, BP and USP methods

Total: 90