

GUJARAT TECHNOLOGICAL UNIVERSITY
M.Pharm.

Pharmaceutical Management and Regulatory Affairs

Proposed Teaching Scheme (W.E.F July 2012)

Semester I

Paper No.	Subject	Teaching Scheme		Evaluation Scheme			
		Credit		Theory		Practical	
		Theory	Practical	External	Internal	External	Internal
910001	Modern Analytical Techniques (Common to all branches)	6	6	80	20	80	20
1911601	cGMP and Documentation	6	6	80	20	80	20
1911602	Pharm management-I	6	0	80	20	-	-

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Pharmaceutical Management and Regulatory Affairs

Subject Code: **910001**

Subject Name: **Modern Analytical Techniques (Common to all branches)**

Theory (60 Hours) (Four hours per week, 6 Credits)

Sr_No	Content	Hr
1.	<p>UV-VISIBLE SPECTROSCOPY : Brief review of electromagnetic spectrum and absorption of radiations. The chromophore concept, absorption law and limitations. Theory of electronic spectroscopy, absorption by organic molecules, choice of solvent and solvent effects. Applications of UV-Visible spectroscopy, Woodward -Fischer rules for calculating absorption maximum, interpretation of spectra, multi-component assay, difference spectra and derivative spectra</p>	05
2.	<p>INFRARED SPECTROPHOTOMETRY : Introduction, basic principles, and sampling techniques, interpretation of spectra, applications in Pharmacy. FT-IR, Attenuated Total Reflectance (ATR), Near infra red Spectroscopy (NIR)-theory and applications.</p>	05
3.	<p>. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY : Fundamental Principle and Theory, Instrumentation, solvents, chemical shift, and factors affecting chemical shift, spin-spin coupling, coupling constant, and factors influencing the value of coupling constant, spin-spin decoupling, proton exchange reactions, simplification of complex spectra, FT-NMR, 2D -NMR and applications in Pharmacy, interpretation of spectra. C13 NMR Introduction, Natural abundance, C13 NMR Spectra and its structural applications.</p>	07
4.	<p>MASS SPECTROMETRY: Basic principles and instrumentation, ion formation and types, fragmentation processes and fragmentation pattern, Chemical ionization mass spectroscopy (CIMS), Field Ionization Mass Spectrometry (FIMS), Fast Atom Bombardment MS (FAB MS), Matrix Assisted laser desorption/ ionization MS(MALDI-MS), interpretation of spectra and applications in Pharmacy.</p>	07
5.	<p>ATOMIC ABSORPTION AND PLASMA EMISSION SPECTROSCOPY: Principle, instrumentation, interferences and applications in Pharmacy.</p>	03

6.	X-RAY DIFFRACTION METHODS : Introduction, generation of X-rays, X-ray diffraction, Bragg's law, X-ray powder diffraction, interpretation of diffraction patterns and applications.	03
7.	OPTICAL ROTARY DISPERSION : Principle, Plain curves, curves with cotton effect, octant rule and its applications with example, circular dichroism and its relation to ORD.	03
8.	THERMAL METHODS OF ANALYSIS : Theory, instrumentation and applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA).	04
9.	CHROMATOGRAPHIC TECHNIQUES: a) Classification of chromatographic methods based on mechanism of separation, Theories of chromatographic separation. b) Principles, elution techniques, instrumentation, derivatization and applications of gas chromatography, HPLC and HPTLC. c) Principles, elution techniques, applications of ion exchange and ion pair chromatography, affinity chromatography, size exclusion chromatography, chiral chromatography, super fluid chromatography (SFC), GC-MS and LC-MS.	15
10.	ELECTROPHORESIS : Theory and principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Isoelectric focusing (IEF) and applications.	03
11.	RADIO IMMUNO ASSAY : Introduction, Principle, Theory and Methods in Radio Immuno Assay, Related Immuno Assay procedures and applications of RIA Techniques. Enzymeimmuno assay- ELISA and EMIT.	03
12.	Reference standards: Source, preparation, characterization, usage, storage and records.	02

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Subject Code:**910001**

Subject Name:**Modern Analytical Techniques (Common to all branches) Practicals**
(Four hours per week, 6 Credits)

1. Use of colorimeter for analysis of Pharmacopoeial compounds and their formulations.
2. Use of Spectrophotometer for analysis for Pharmacopoeial compounds and their formulations.
3. Simultaneous estimation of combination formulations (minimum of 4 experiments): e.g.
 - a. Vitamins
 - b. Oral antidiabetics
 - c. NSAIDs
 - d. Antimicrobials
 - e. Antihistamines
 - f. Antihypertensive etc.
4. Effect of pH and solvent on UV Spectrum of certain drugs.
5. Experiments on flame photometry.
6. Use of fluorimeter for analysis of Pharmacopoeial compounds.
7. Experiments on Electrophoresis.
8. Experiments of Chromatography.
 - a. Thin Layer Chromatography.
 - b. Paper Chromatography.
9. Experiments based on HPLC & GC.
10. IR, NMR and Mass Spectroscopy - Interpretation of spectra & Structural elucidation (atleastfor 4 compounds each).
11. Any other relevant exercises based on theory.

Recommended books:

1. Spectrometric identification of Organic Compounds, Robert. M. Silverstein, Basseler, Morrill(John Wiley and Sons. N.Y).
2. Spectroscopy of Organic Compounds by P. S. Kalsi.
3. Principles of Instrumental Analysis by Douglas A. Skoog, James, J. Leary, 4th Edition.
4. Pharmaceutical Analysis - Modern Methods - Part A, Part B, James W. Munson 2001.
5. Organic Spectroscopy - William Kemp, 3rd Edition.
6. Chromatographic Analysis of Pharmaceuticals, John A. Adamovics, 2nd Edition.

7. Practical Pharmaceutical Chemistry, Part two, A. H. Beckett & J. B. Stenlake - 4th edition.
8. Instrumental Methods of Analysis - Willard, Merritt, Dean, CBS, Delhi.
9. Techniques and Practice of Chromatography - Raymond P. W. Scott, Vol. 70.
10. Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography - P. D. Sethi, DilipCharegaonkar, 2nd Edition.
11. HPTLC - Quantitative Analysis of Pharmaceutical Formulations - P. D. Sethi.
12. Liquid Chromatography - Mass Spectrometry, W. M. A. Niessen, J. Van Der Greef, Vol. 58.
13. Modern Methods of Pharmaceutical Analysis, Vol.1, 2, RE Schirmer, Franklin Book
14. Colorimetric Methods of analysis- F. D. Snell and C. T. Snell (Van Nostrand Reinhold Company, N.Y.).
15. Indian Pharmacopoeia
16. British Pharmacopoeia
17. U.S. Pharmacopoeia
18. Clarke's Analysis of Drugs and Poisons, A.C.Moffat, M. David Osselton, Brain Widdop, L. Y. Galichet. 3rd edition, Pharmaceutical Press
19. Text book of Pharmaceutical Analysis, K. A. Connors, 3rd Ed., John Wiley & Sons, New York.

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Subject Code: 1911601

Subject Name:cGMP and Documentation(Theory)

(Four hours per week, 6 Credits) Total: 60 hours

Sr_No	Content	Hr
1.	Concepts of Philosophy of QA, GMP, GLP	3
2.	Good Manufacturing Practices:	
3.	Organization & Personnel, responsibilities, training, hygiene.	3
4.	Premises: Location, design, Plant Layout, Construction, Maintenance and Sanitation, Environmental control, utilities and services like gas, water, maintenance of sterile areas, and control of contamination.	4
5.	Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place, Methods (TP & STP).	4
6.	Raw Materials: Purchase specifications, maintenance of Stores, selection of Vendors, control on raw materials and finished dosage forms.	2
7.	Manufacture of & control on dosage forms: manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities.	8
8.	In Process quality controls on various dosage forms: Sterile and non sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc.	5
9.	Packaging and labeling control, Line clearance, reconciliation of labels, cartons and other packaging materials.	2
10.	Quality control Laboratory: Responsibilities. Routine controls instruments, reagents, sampling plans, standard test Procedures, protocols, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities.	6
11.	Finished product release, quality review, quality audits and batch release documents.	3
12.	Warehousing, design, construction, maintenance and sanitation; good warehousing practice, materials and management.	2
13.	Distribution and distribution records, handling of returned goods, recovered materials and reprocessing.	2

14.	Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.	2
15.	Waste disposal, scrap disposal procedures and records.	2
16.	Good Laboratory Practices.	4
17.	WHO certification/ICH guidelines and other international guidelines such PICS, EMA & FDA guidelines.	
18.	BMS & other data acquisition systems and softwares	2
19.	Testing of Packaging materials.	2
20.	Quality Audit.	2
21.	Specifications for materials, intermediates and finished product.	2

Recommended books:

1. Sidney H. Willig, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 109, Marcel Dekker Inc., N.Y.
2. S. Bolton, "Pharmaceutical Statistics: Practical & Clinical Applications", Drugs and Pharm. Sci. Series, Vol. 135, 4th Ed., Marcel Dekker Inc., N.Y
3. G. S, Banker & C.T. Rhodes, "Modern Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 121, 4th Ed., Maracel Dekker Inc., N.Y.
4. P. P .Sharma "How to practice GMPs", 3rd edition Vandana Publication.
5. P. P. Sharma "How to practice GLP" Vandana Publication.
6. S. Weinberg, "Good Laboratory Practice Regulation" Drugs and Pharm. Sci. Series, Vol. 124, 2nd Ed., Maracel Dekker Inc., N.Y.
7. WHO's "Drug" Bulletins.
8. Remingtons "Pharmaceutical Sciences".
9. GMP practices for pharmaceutical-James Swarbrick

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Subject Name:**cGMP and Documentation(Practical)**

(Four hours per week, 6 Credits)

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.

I) Practical on the basis of validation approach:

- Analytical methods;
- Process
- Equipment including computer validations

II) Calibration of equipments

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Subject Code: 1911602

Subject Name: Pharm management-I(Theory)

(Four hours per week, 6 Credits) Total: 60 hours

Sr No	Content
1.	Pharmaceutical Management: Meaning, Evolution-scientific, administrative and human relation approach. Process of management: Planning, organizing, staffing, directing, coordinating and controlling-a preliminary idea of concepts, processes and techniques.
2.	Fundamental concepts of production, financial, personal, legal and marketing functions with special reference to Pharmaceutical Management. Introduction to budgeting, costing, accounting, auditing and budgetary control. Entrepreneurship development.
3.	Understanding organizations: Meaning, process, types of organization structures and departmentation, line/staff authority, promoting organizational culture. Organizations, pharmaceutical services and functioning of hospital pharmacy, bulk drug unit, formulation unit, Ayurvedic and Unani manufacturing units and testing labs etc.
4.	Professional Managers; Tasks, responsibilities and skills needed. Leadership; Styles and managing change. Decision Making; Types, procedures, evaluation and selection of alternatives, decision making under various situations. Management information and decision support systems and time management.
5.	Personnel Management: Job Analysis, recruitment, selection, orientation and training, performance appraisal and compensation. Retrenchment, lay off and discharge.
6.	Management of Industrial Relations: Industrial disputes, settlement of disputes through various routes such as bargaining, etc.
7.	Motivational aspects, theories of motivation, group dynamics, rewards and incentives, interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management.
8.	Stress management.
9.	Project management and new enterprise management (NEM)

Reference Books :

1. Marketing Management by Philip Kotlar; Prentice-Hall of India Ltd., New Delhi.
2. Management and Organization by Louis A. Allen; McGraw Hill, Tokyo..
3. Corporate Strategy by Ansoff, H.T.; McGraw Hill, New York.
4. Modern Management by Hempran David R.; McGraw Hill, New York.
5. Management by Stoner and Freeman; Prentice Hall, New Delhi.
6. Motivation and Personality by Maslow, Abraham, Harper & Row, New York.
7. Management of Organizational Behavior, Utilizing the Human Resources by Harcey, Paul and Blanchard Kenneth; Prentice Hall of India, New Delhi
8. Organization Structure, Process and out comes V th Edition Richard. H. Hall
9. Principles and Methods of Pharmacy Management III rd Edition Harry A. Smith.
10. Management “Global Perspective Heinz Wehrich, Harold Koontz by Tata Mcgraw Hill”.
11. Personnel Management and Industrial Relations by P. C. Tripathi.