Gujarat Technological University

M. Pharm.

QUALITY ASSURANCE AND REGULATORY AFFAIRS

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

Semester – I

Paper No.	Subject	Teaching scheme		Teaching scheme		Teaching scheme	
		Credit		Theory		Practical	
		Theory	Practical	External	Internal	External	Internal
910001	Modern Analytical Technique	6	6	80	20	80	20
910104	Biological evaluation and clinical research	6	6	80	20	80	20
1911502	Basic concepts of Regulatory affairs	6	--	80	20		

GUJARAT TECHNOLOGICAL UNIVERSITY
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Quality Assurance 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.	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	**05**
2.	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.	**05**
3.	. 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 NMRIntroduction, Natural abundance, C13 NMR Spectra and its structural applications.	**07**
4.	MASS SPECTROMETRY: Basic principles and instrumentation, ion formation and types, fragmentation processes andfragmentation pattern, Chemical ionization mass spectroscopy (CIMS), Field Ionization MassSpectrometry (FIMS), Fast Atom Bombardment MS (FAB MS), Matrix Assisted laser desorption/ ionization MS(MALDI-MS), interpretation of spectra and applications inPharmacy.	**07**
5.	ATOMIC ABSORPTION AND PLASMA EMISSION SPECTROSCOPY: Principle, instrumentation, interferences and applications in Pharmacy.	**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, derivatizationand 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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Quality Assurance and Regulatory Affairs

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 Pharmacopoieal 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, Morril(John Wiley and Sons. N.Y).

2. Spectroscopy of Organic Compounds by P. S. Kalsi.

3. Principles of Instrumental Analysis by Donglas 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: 910104

Subject Name: Biological Evaluations and Clinical Research

Theory (Four hours per week, 6 Credits)

Sr_No	Content	Hr.
1.	**Biological Standardization:** General Principles, Scope & limitations of Bioassays. Bioassays of some Official Drugs.	04
2.	**Sterility Tests:** Methodology & Interpretation.	04
3.	**Pyrogen -** chemistry and properties of bacterial pyrogens and endotoxins. Mechanisms of action of pyrogens. Pharmaceutical aspects, pyrogen test of IP compared to that of BP & USP. Interpretation of data, Comparison of LAL and other pyrogen tests.	05
4.	Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration.	05
5.	**Microbiological Limit Tests,** Tests for effectiveness of antimicrobial preservatives.	06
6.	**Radio immunoassay:** General principles, scope and limitations, radio immunoassay of some drugs like insulin, digitalis etc.	04
7.	Preclinical Drug Evaluation, acute, sub acute and chronic toxicity studies, LD50 & ED50 determination, evaluation of compound for its biological activity, study of special toxicities like teratogenicity and mutagenicity.	07
8.	**Clinical Research—** **a.** Clinical Research Protocols, objective and protocol design. **b.** Helsinki declaration, US-FDA & ICH guideline for Clinical trials for drugs and dosage forms, reviews and approval of Clinical Study.	10

	c. Good Clinical Practices.	
9.	**Bioavailability:-** Objectives and consideration in bio-availability studies, Concept of equivalents, Measurements of bio-availability, Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems.	**07**
10.	**Pharmacokinetics:-** Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development and designing of dosage forms and Novel drug delivery systems.	**08**

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Subject Code: 910104

Subject Name: Biological Evaluations and Clinical Research

Practical (Four hours per week, 6 Credits)

1. Bio-analytical method development and its validation.
2. Analysis of biological fluids.
3. Analysis of drug in biological fluids.
4. Dissolution study of simple and modified release solid oral dosage forms.
5. Any other relevant exercises based on theory.

Reference Books:

1. Indian Pharmacopoeia
2. British Pharmacopoeia
3. U.S. Pharmacopoeia
4. Bengt Ljunggvist and Berit Davis “Microbiological Risk Assessment in Pharm. Clean rooms”. Harwood International Publishing.
5. Richard Prince, “Microbiology in Pharmaceutical Manufacturing”. Davis Harwood International Publishing.
6. Akers, “Parenteral Quality Control: Sterility, Pyrogen, and Package Integrity Testing,” 2nd Edition (Marcel Dekker).
7. D. C. Garratt, The Quantitative Analysis of Drugs, CBS Publishers, 2001, New Delhi..
8. Mark C. Rogge and David R Taft, “Prclinical Drug Development”, Drugs and Pharm. Sci. Series, Vol. 152, Marcel D
9. ekker Inc., N.Y.

11. Donald Monkhouse, Charles Carney and JimClark, “Drug Products For Clinical Trials”. 2nd Ed. v Drugs and Pharm. Sci. Series, Vol. 147, 2nd Ed., Marcel Dekker Inc., N.Y.
12. Leon Shargel, “Applied Biopharmaceutics and Pharmacokinetics”.
13. Welling and Tse.-Pharmacokinetic
14. Gibaldi and Perrier-Pharmacokinetics
15. G. S, Banker & C.T. Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 121, 4th Ed., Maracel Dekker Inc., N.Y.
16. Rowland and Tozer-Clinical Pharmacokinetics, concepts and application.
17. Notari.-Biopharmaceutics and Pharmacokinetics-An introduction.
18. John Wagner- Pharmacokinetics for Pharmaceutical scientist.
19. R V Smith, J T Stewart, Textbook of Bio Pharmaceutical Analysis

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Quality Assurance and Regulatory Affairs

Subject Code: 1911502

Subject Name: Basic Concept of Regulatory Affairs Theory

(Four hours per week, 6 Credits)

Sr_No	Content
1.	Basic concepts of Quality control & Quality Assurance, Total Quality Management, Philosophy of GMP, cGMP, GLP, ISO. Introduction of ICH guidelines.
2.	Organization & functions of the Federal Food & Drug Administration of USA. Federal trade commission Act. The Environmental Pollution Control Act, Other laws related to pharmacy including Tort law, Contract law etc.
3.	III. A detailed study of Food & Drug Laws affecting drug products design, manufacture and distribution in USA. • The Federal Food. Drugs & Cosmetics Act 1938. • Druham – Humphrey Amendment 1951. • Kefauver – Harris Amendment 1962. • The Drug Listing Act 1972 • Prescription Drug Marketing Act 1987
4.	Concept and historical development of pharmaceutical product registration. Effect of GATT and WTO on commerce of pharmaceuticals. Introduction to Intellectual Property Rights.
5.	Globalization of drug industries, Export Import Policy of drugs, WHO – certification, Trademarks and copyrights.

6.	Regulation & licensing of drugs & cosmetics – recent amendments and other relevant rules. Consumer protection, Factory Act, Loan license.

Recommended Books

1) Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices by John J. Tobin and Gary Walsh
2) FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Second Edition by Do uglas J. Pisano and David S. Mantus
3) Good Drug Regulatory Practices: A Regulatory Affairs Quality Manual (Good Drug Development Series, Vol 1) by Helene I. Dumitriu
4) Pharmaceutical Patent Law by John R. Thomas