Gujarat Technological University
M. Pharm. Syllabus
Semester I
Paper Code 910001
MODERN ANALYTICAL TECHNIQUES
(Common to all disciplines)
Theory

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.

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.

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 NMR-Introduction, Natural abundance, C13 NMR Spectra and its structural applications.

4. 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.

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.

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.

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).

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, and chiral chromatography, super fluid chromatography (SFC), GC-MS and LC-MS.

10. ELECTROPHORESIS:
Theory and principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Isoelectric focusing (IEF) and applications.

11. RADIO IMMUNO ASSAY:
Introduction, Principle, Theory and Methods in Radio Immuno Assay, Related Immuno Assay procedures and applications of RIA Techniques. Enzyme immuno assay- ELISA and EMIT.

12. Reference standards source, preparation, characterization, usage, storage and records.

MODERN ANALYTICAL TECHNIQUES
Practicals

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 (atleast for 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 dition.
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, Dilip Charegaonkar, 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 Text book of Pharmaceutical Analysis, K. A. Connors, 3rd Ed., John Wiley & Sons, New York.

Gujarat Technological University
M. Pharm. Syllabus
Semester I
Paper Code:910104
QUALITY ASSURANCE SPECIALISATION
Biological Evaluations and Clinical Research
Theory

Course Content:

1. **Biological Standardization:** General Principles, Scope & limitations of Bioassays. Bioassays of some Official Drugs.

2. **Sterility Tests:** Methodology & Interpretation.

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.

4. Analysis of drugs from biological samples including, selection of biological sample, extraction of drugs by various methods as LLE, SPE and Membrane filtration.

5. Microbiological Limit Tests, Tests for effectiveness of antimicrobial preservatives.

6. **Radio immunoassay:** General principles, scope and limitations, radio immunoassay of some drugs like insulin, digitalis etc.

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.

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.
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.

10. **Pharmacokinetics:-** Basic consideration, Pharmacokinetic models, Application of Pharmacokinetics in new drug development and designing of dosage forms and Novel drug delivery systems.

BIOLOGICAL EVALUATION AND CLINICAL RESEARCH
Practical

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.

Gujarat Technological University
M. Pharm. Syllabus
Semester I
Paper Code 910204
QUALITY ASSURANCE SPECIALISATION
Good Manufacturing and Good Laboratory Practice
Theory

Course Content:

1. Concepts of Philosophy of QA, GMP, GLP

2. Good Manufacturing Practices:

a. Organization & Personnel, responsibilities, training, hygiene.

b. 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.

c. Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place, Methods (TP & STP).

d. Raw Materials: Purchase specifications, maintenance of Stores, selection of Vendors, control on raw materials and finished dosage forms.

e. Manufacture of & control on dosage forms: manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities.

f. 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.

g. Packaging and labeling control, Line clearance, reconciliation of labels, cartons and other packaging materials.

h. 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.

i. Finished product release, quality review, quality audits and batch release documents.

j. Warehousing, design, construction, maintenance and sanitation; good warehousing practice, materials and management.

k. Distribution and distribution records, handling of returned goods, recovered materials and reprocessing.

l. Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.

m. Waste disposal, scrap disposal procedures and records.

3. Good Laboratory Practices.

4. WHO certification.

5. Testing of Packaging materials.

6. Quality Audit.

7. Specifications for materials, intermediates and finished product.

Reference 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 Pharmaceutics", 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.