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.

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.

Semester I

Paper code-910102

Subject: - Specialization Paper-I

Pharmaceutical Formulation, Development & Bio pharmaceutics

Theory

1. Preformulation studies

(a) Physical, Chemical and Pharmaceutical factors influencing formulation

(b) Solid-state characterization: Crystallinity, hygroscopicity, Particle size and particle size distribution, compaction properties

(c) Crystalline and polymorphism and its evaluation. Rationale for selecting the preferred polymorph/crystalline form

(d) General principles and applications of various characterization techniques viz: Differential thermal analysis Differential scanning calorimetry, X-Ray diffraction, FTIR in Preformulation study.

(e) Drug-excipient compatibility study

(f) Traces of organic volatile impurities (OVIs) and their regulatory limits (residual Solvents).

(g) Preformulation studies of Biotechnological derived products and reference guidelines.

2. Solubilization and solubilized system

(a) Theoretical aspects and applications.

(b) Techniques for improvement in drug solubilization for development of various dosage forms.

3. Dissolution study

(a) Importance, objectives, equipments,

(b) Biological classification system (BCS); its significance on dissolution study and application in dosage form development.

(c) Selection of dissolution media and conditions.

(d) Comparison of dissolution profile by model independent (similarity and dissimilarity factor) and dependent methods.

4. Stability Study

(a) Basic concept and objectives of stability study,

(b) Order of reaction and their applications in predicting shelf life & half life of pharmaceutical formulations,

(c) Importance of accelerated stability study,

(d) Effect of various environmental/ processing factors like light, pH, temperature, etc. on stability of the formulation and techniques for stabilization of product against the same.

(e) Regulatory requirements related to stability testing with emphasis on matrixing/bracketting techniques, climates zone, impurities in stability study, photostability testing etc.,

(f) Applications of microcalorimetry in stability study.

5. Drug Absorption

(a) Factors affecting drug absorption; i.e. Physicochemical, Physicality and Pharmaceutical.
(b) Method of studying bioavailability and bioequivalence.
(c) Transport across CACO 2 monolayers, Other Cell-lines to predict- Biological, Pharmaceutical and Analytical considerations

6. Pharmacokinetic parameters

(a) Basic concept and importance of biological half-life, volume of distribution, renal clearance, total body clearance, plasma protein binding, and absorption rate constant, elimination rate constant.
(b) Analysis of blood and urine data, compartment models, kinetics of one and two compartment model.

7. In-vitro In-vivo Correlation (IVIVC)

(a) Methods of establishing IVIVC
(b) Factors affecting IVIVC

8. Cosmetic, Dental and Herbal products

(a) Formulation and evaluation of various cosmetic and dental products
(b) Formulation and evaluation of products containing herbal ingredients.

Reference Books:

1. **Remingtons** "Pharmaceutical Sciences" 19th edition.
2. **Lachman "**The theory and Practice of Industrial Pharmacy" 3rd edition.
3. Pharmaceutics "The Science of Dosage form design" **by Aulton**
4. Pharmaceutical dispensing **by Husa**.
5. Modern pharmaceutics **by G. S. Banker.**
6. Encyclopedia of pharmaceutical technology Volumes: 1 to 19.
7. Pharmaceutical dissolution testing **by Banaker.**
8. United States Pharmacopeia.
9. Techniques of Solubilization of Drugs **by Yalkowsky.**
10. Drug stability (Principles and Practices) **by Jens. T. Carstensen.**
11. Stability of drug and dosage forms **by Yoskioka.**
12. Applied Biopharmaceutics and pharmacokinetics by **Leon Shargel**, 4th edition.
13. Pharmacokinetics **by Welling and Tse.**
14. Pharmacokinetics **by Gibaldi and Perrier**
15. Biopharmmaceutics and pharmacokinetics: An introduction **by Notari.**
16. Pharmacokinetics for pharmaceutical scientist **by John Wagner.**
17. Dissolution, Bioavailability and Bioequivalence **by Abdul.**

18. Clinical Pharmacokinetics, Concepts and applications **by Rowland and Tozer.**
19. Novel Cosmetic Drug Delivery Systems, **by Magdassi and Touitou.**
20. Cosmetics **by Sagerin.**
21. Perfumes, Cosmetics and Soaps **by Poucher.**

Pharmaceutical Formulation, Development & Bio pharmaceutics

Practicals

1. To prepare, evaluate and supply microspheres.
2. To prepare, evaluate and supply Aspirin microspheres.
3. To prepare, evaluate and supply microcapsules.
4. To prepare, evaluate and supply Aspirin Effervescent Tablets.
5. To prepare, evaluate and supply Chewable Antacid Tablets.
6. To prepare, evaluate and supply Floating Tablets.
7. Direct Warm Spheronization.
8. To prepare and evaluate Suppositories.
9. To prepare, evaluate and supply Cold Cream.
10. To optimize the formula for vanishing cream and to evaluate it.
11. To prepare Toothpaste.
12. To optimize the formula for gel and to evaluate it.
13. To optimize the formula for Lather Shaving Cream and to evaluate it.
14. Tablet Coating (Dip Coating)
15. Preparation and evaluation of multiple emulsion.
16. To carry out pan coating of tablets.
17. Preparation and evaluation of Fast Dispersible Tablets.

Semester I

Paper code-910202

Subject: - Specialization Paper-II

Industrial Pharmacy

Course Content:

1. Pharmaceutical factory location: Selection, layout and planning.
2. Utility services, Service facilities, HVAC and personnel facilities.
3. Preparation of qualitative and quantitative departmental layout with equipments
4. Required for different dosage forms, solids, liquids, semisolids, sterile.
5. Detailed study of the equipments required in the manufacture of different dosage
6. Forms as per Schedule-M.
7. Preparation of documents like batch manufacturing record, batch packing record,
8. Validation protocols.
9. Preparation of standard operative procedure (SOPs) for equipments
10. And manufacturing or processing steps.
11. GMP and its implementation
12. Production planning and materials control.
13. Pilot plant, scale up technique.

Reference Books:

1. **Lachman** "The theory and Practice of Industrial Pharmacy
2. **Remingtons** "Pharmaceutical Sciences"
3. Bentley's **Pharmaceutics.**
4. Pilot plants model and scale-up methods**, by Johnstone and Thring.**
5. GMP practices for pharmaceutical –**James Swarbrick.**
6. How to practice GMP**s by P.P.Sharma.**
7. Chemical Engineering Plant Design **by Vibrant.**
8. Pharmaceutical Process Validation **by Loftus and Nash.**
9. Drug and Cosmetic Act 1940 and rules.