GUJARAT TECHNOLOGICAL UNIVERSITY
BACHELOR OF PHARMACY
SEMESTER: VIII

Subject Name: **Pharmaceutical Analysis - IV**
Subject Code: **280004**

[THEORY]

Sr. No.	Course Contents	Total Hrs
1.	**X-ray spectroscopy** Introduction; Generation of X – rays; X-ray diffraction, Bragg's law; Applications of X- ray diffraction.	04
2.	Overview of Scattering Spectroscopy like Raman spectroscopy, Nephlometry and turbidimetry.	03
3.	**Gas Chromatography** Introduction; Theory and Principle of Gas-Chromatography; Mobile phase, Stationary phases for GSC and GLC; Instrumentation (including temperature programming and derivatization) and applications of GC; Overview of GC-MS.	06
4.	**High Performance Liquid Chromatography** Introduction; Theory, Classification and Principle of HPLC; Mobile phase, Stationary phases for normal and reversed phase HPLC; Instrumentation (including significance of guard column) and applications of HPLC; Comparison of HPLC with GC; Overview of LC-MS, LC-MS/MS. Basic principle, theory and applications of partition, adsorption, ion-exchange, size exclusion, Super critical fluid and Affinity chromatography.	13
5.	**HPTLC** Principle; Comparison with HPLC; Instrumentation, applications, advantages and limitations of HPTLC.	02
6	**GLP:** Introduction; History, basic issues and quadrants of GLP; Responsibilities matrix; Calibration and Testing.	03
	IPR: Introduction; Steps of filing patents and Introduction of GATT and TRIPS.	02
	ISO: Elements; Requirements and Interpretation of ISO 9001:2000; Quality Management System.	03
	AMV: Analytical method validation; Validation parameters as per ICH guidelines.	02

7.	**Radiochemical methods** Introduction; Nuclear reactions and radiation; Interaction of nuclear radiation with matter; Radioactive decay; Units of radioactive decay; Measurement of radioactivity; Activity analysis; Isotopes dilution analyses; Liquid scintillation systems; Applications of radio nuclides	05
8.	Overview of radio-immuno assay (RIA) and ELISA (Immunochemical techniques).	02

Note:

Examples based on assays & structure elucidation shall be covered at concerned subtopics in each of the following chapters.

[PRACTICALS]

Note:

Following Experiments shall include different dosage forms & pharmacopoeial testing from different pharmacopoeias, wherever applicable.

Sr. No.	Course Contents
1.	Separation and identification of drugs/impurities/related substances by TLC methods as per I.P.(Three experiments)
2.	Separation and identification of amino acids/flavonoids/sulphonamides by paper chromatography. (min. one experiment)
3.	Quantitative analysis of market formulations by HPLC/GC. (Two demonstrative experiments)
4.	Potentiometric assay of any two formulations from I.P. (e.g. Sulpha drug, INH, penicillins)
5.	Assay of dextrose injection by polarimetry
6.	Evaluation of Monographs as per I.P. (Any Two): Complete testing including assay.
7.	Karl-fischer Titration
8.	Pharmacopoeial standards of waters by Conductometry
9.	Assay of drugs by aqueous & non-aqueous pH-metry titration. (Two experiments)

Text Books:

1. Principles of Instrumental Analysis by Skoog, Holler and Nieman, 5th edition.
2. Instrumental methods of Analysis, H.H. Willard, L.L. Meritt, J.A. Dean and F.A. Settle Wadsworath , New York.

Reference Books:

1. Pharmaceutical Analysis: Modern methods Part A, Part B, James W. Munson.
2. Quality Assurance Guide by Organization of Pharmaceutical Products of India.
3. S. Weinberg, "Good Laboratory Practice Regulation" Drugs and Pharm. Sci. Series, Vol. 124, 2nd Ed., Marcel Dekker Inc., N.Y.
4. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials – Vol. I – WHO Publications.
5. IPR Handbook for Pharma Students and researchers – Parikshit Bansal, Pharma Book Syndicate, Hyderabad
6. Pharmacopoeia of India, Govt. of India, Ministry of Health.
7. British Pharmacopoeia, ministry of health and social welfare, UK.
8. The United States Pharmacopeia–National Formulary (USP–NF)