GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm

SEMESTER: VI

Subject Name: Pharmaceutical Analysis IV
Subject Code: 2260003

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	3	6	80	20	80	20

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	Radio chemical 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
7	Overview of radio-immuno assay (RIA) and ELISA (Immunochemical techniques).	02
8	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

Note:

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

Practical – 22600P3

Sr. No.	Content
1	Quantitative analysis of market formulations by HPLC (Demo)
2	Quantitative analysis of market formulations by HPTLC (Demo)
3	Quantitative analysis of market formulations by GC (Demo)
4	Evaluation of Monographs as per I.P. : Complete testing including assay.
5	Colorimetric assay of non coloured drugs by derivatization method
6	Colorimetric assay of colored compound
7	Evaluation of linearity, range and accuracy of UV method
8	Evaluation of linearity, precision and robustness of UV method
9	Simultaneous estimation of drug by derivative or difference spectroscopy
10	To determine isoabsorptive point of two/three different drugs for selection of wavelength in HPLC for binary/ternary mixture
11	Determination of total sugar in fruits/jams
12	Determination of vitamin C in fruit juice
13	To determine total glucose in different brands of honey
14	Determination of total ash content in **food product**
15	Determination of **food additives** like preservatives, colors and flavours
16	Assay of **antibiotic** by nephelometry
17	To perform QC testing tablets
18	To perform QC testing tablets
19	To determine the % purity of Isoniazid and Rifampicin in combination tablets.
20	Separation and identification of slupha drugs by TC techniques

References Books:

1. Principles of Instrumental Analysis by Skoog, Holler and Nieman, 5^{th} edition.
2. Instrumental Methods of Analysis, H.H. Willard, L.L. Meritt, J.A. Dean and F.A. Settle Wadsworath , New York.
3. Pharmaceutical Analysis: Modern methods Part A, Part B, James W. Munson.
4. Quality Assurance Guide by Organization of Pharmaceutical Products of India.
5. "Good Laboratory Practice Regulation" Drugs and Pharm. Sci. Series, Vol. 124, 2nd Ed., S. Weinberg, Marcel Dekker Inc., N.Y.
6. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials – Vol. I – WHO Publications.
7. IPR Handbook for Pharma Students and researchers – Parikshit Bansal, Pharma Book Syndicate, Hyderabad
8. Pharmacopoeia of India, Govt. of India, Ministry of Health.
9. British Pharmacopoeia, ministry of health and social welfare, UK.
10. The United States Pharmacopeia–National Formulary (USP–NF)