Expertise in spectroscopic and chromatographic techniques through advanced instrument training (CED)

Theory and Practice of Spectroscopic and Chromatographic Techniques Through a\Advanced Instrument

Teaching Scheme/week (hr)				Evaluation Scheme			
				Theory		Practical	
Theory	Communication & Soft Skill Development	Practical	Total	End Term Evaluation	Mid Term Evaluation	End Term Evaluation	Mid Term Evaluation
10	05	20	35	70	30	70	30

Objectives: Upon completion of the course the student shall be able to

1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis.
2. Understand the chromatographic separation and analysis of drugs
3. Perform quantitative & qualitative analysis of drugs using various analytical instruments.
4. Acquire knowledge of Validation and various regulatory Guidelines

THEORY (10 hr/week, Total:100 hr)

Sr. No.	Course Content	hr
Module 1. Titrimetric Analysis	**1.1 Basic introduction of aqueous and non-aqueous titration and its application in pharma industry.**	2
	1.2 Electrochemical methods of analysis **1.2.1 Potentiometric and PH metric analysis:** Basic Principals, different electrodes, Potentiometric Titrations, Ion Selective Electrodes, Applications of Potentiometric Titration, calibration of PH Mete, **Determination of moisture Content (LOD) by Karl-Fisher titration and its impact in analysis**	5
Module 2 (Spectroscopy)	**2.1 Fundamentals of Spectroscopy:** Classification of spectra i.e. line, band, continuous spectra / absorption, emission spectra; Wave properties of electromagnetic radiation; Particle/photon properties of electromagnetic radiation; Electromagnetic spectrum.	03
	2.2 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, Estimation of fix dose	11

	combination (FDC), difference spectra and derivative spectra, and its Qualitative and Quantitative Applications.	
	2.3 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 its Qualitative and Quantitative applications.	**06**
	2.4 NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY: Fundamental Principle and Theory, Instrumentation.and its Applications in pharmaceutical Industry.	**02**
	2.5 MASS SPECTROMETRY: Basic principles and instrumentation its applications in Pharmacy.	**02**
	2.6 ATOMIC ABSORPTION AND PLASMA EMISSION SPECTROSCOPY: Principle, instrumentation, Absorption and Emission spectra, Elemental Impurity analysis, Elemental impurity risk assessment and its Application in pharmacy	**05**
	2.7 X-RAY DIFFRACTION METHODS: Introduction, and its applications.	**02**
	2.8 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).	**05**
Module 3. (Chromatographic Techniques)	**3.1 CHROMATOGRAPHIC TECHNIQUES:** Classification of chromatographic methods based on mechanism of separation. Theories of chromatographic separation. Principles, Column Chemistry, Column Qualification & elution techniques, Scientific approach of analytical method development, Instrumentation, derivatization and applications of gas chromatography, HPLC and HPTLC) Principles, elution techniques, applications of ion exchange, ion pair chromatography, affinity chromatography, size exclusion chromatography, chiral chromatography, super fluid chromatography (SFC), GC-MS, Applications of LC-MS, and LC-MS/MS in identification and characterization of Impurity	**30**
Module 4. (Q.A)	**4.2 Brief Introduction of QA** ICH (Q1, Q2,Q3, Q4, Q6, Q9, Q14) & USFDA guidelines related to analytical methods. WHO and USFDA document for technology transfer. Introduction to various pharmacopoeia and monograph of various dosage form, process validation and cleaning validation	**10**
	4.2 Stability Testing & Stabilization of Pharmaceuticals: Basics of stability; types of stability testing (accelerated, real time and stress	**07**

	testing), regulatory requirements for stability testing: approaches for stabilization.	
	4.3 Application of Statistics in Analytical Techniques: Basic concept of bio- Statistics ANNOVA, t-test and F-test etc, significance of p value in ANOVA.	04
Module 5. (R.A)	**5.1 Basics of Various Phases of Drug Development & Approval:** INDA, NDA & ANDA; Requirements of regulatory agencies for generic product development; Basic of patents & IPR.	04
	5.2 Recent advances in pharmaceutical analysis	02
	Total (Theory)	100

PRACTICAL (20 hr/week, Total:200 hr)

PRACTICALS

Practical 1 : Calibration of Volumetric apparatus.

Practical 2-6: Calibration of various instruments (i.e., Electronic balance, pH meter, UV Spectrophotometry, HPLC, Dissolution test apparatus etc.)

Practical 7- Preparation of normal and molar solution, dilution of analytical samples.

Practical 8-11: Assay of drugs by various techniques using UV Spectroscopy

Practical 12-14: Method validation for various analytical techniques by UV Spectroscopy

Practical 15-17: Colorimetric estimation of non-colored, & colored drugs.

Practical 18: Determination of moisture content from drug/ excipient by Karl-Fischer titration.

Practical 19: Identification of API/ Qualitative analysis of given samples by FT-IR.

Practical 20: Metal ion analysis by Flame photometry.

Practical 21: Thin Layer Chromatography of Pharmacopoeial compounds

Practical 22: Paper Chromatography of Amino acids

Practical 23: Method development of drugs by HPLC.

Practical 24: Method validation by HPLC.

Practical 25: Stability Indicating Assay method by HPLC.

Practical 26: Dissolution study/ profile by USP Dissolution test apparatus.

Practical 27-30: Workshops on structure elucidation by UV, IR, NMR & MASS.

Practical 31-32: Workshops related application of DSC and X-ray Spectroscopy in formulation development

Practical 33-36: Assay of Pharmacopoeial drugs as per IP & USP.

Practical 37-38: To perform Monographs of drugs as per IP & USP.

Practical 39-40: Workshops to study various tests as per Appendix of Pharmacopoeias.

Practical 41: Demonstration/ Assay of drugs by various instruments like GC/HPTLC/LC-MS.

Communication, Soft Skill Development & subjective presentations (05 hr/week, Total: 50 hr)

Importance of communication and communication process. Verbal and Non-verbal communication (understanding body language), Listen skills (active, passive and reflective listening), preparing for interview, Interview Structure and Interview. Subjective seminar and presentation. Presentation for interview.