CHE-321-VSC-T: PHARMACEUTICAL ANALYTICAL CHEMISTRY

Course Type: VSC **Credits: 2**

A. Course Objectives:

1. To introduce fundamental concepts of pharmaceuticals and analytical chemistry.
2. To develop understanding of drug composition, dosage forms, and pharmacopoeial standards.
3. To impart knowledge of physicochemical properties of drugs such as pH, solubility, and stereochemistry.
4. To familiarize students with impurity testing and quality control methods.
5. To provide basic understanding of instrumental techniques (UV, IR, HPLC, optical rotation) in pharmaceutical analysis.
6. To develop skills for analysis and quality evaluation of pharmaceutical formulations.

B. Course Outcomes (COs):

CO No.	Course Outcome Statement (COs) *After learning the course, the students are able to -*
CO-1	Recall basic concepts of pharmaceuticals, dosage forms, and analytical terms.
CO-2	Explain physicochemical properties and impurity testing methods of drugs.
CO-3	Apply analytical techniques for identification and assay of pharmaceuticals.
CO-4	Analyze data obtained from UV, IR, HPLC, and optical rotation methods.
CO-5	Evaluate quality and purity of pharmaceutical formulations using standards.
CO-6	Design suitable analytical approaches for drug analysis and quality control.

C. Contents:

Prerequisites	
Students should have basic knowledge of organic and physical chemistry, including acids, bases, pH, and chemical bonding. Familiarity with basic analytical techniques and laboratory practices is desirable. An introductory understanding of spectroscopic and chromatographic methods will help in better comprehension of pharmaceutical analysis.	
Chapter 1: Introduction to Pharmaceuticals and its Analytical Chemistry	**10 Hours**
Part-A: Some definitions: Pharmaceuticals Active Pharmaceutical ingredients (API), Excipients, Solvents. **Pharmaceutical dosage forms (definitions):** Tablets, Capsules, powders, syrup, suspensions, solutions, injections, sprays / aerosols, pests, creams, gels. **(Ref-**	

2) **Part-B:** Introduction, Pharmaceutical Analysis -A brief definition, Manufacture of pharmaceuticals, Development of new drugs, Use of pharmaceuticals; Marketing Authorization and Industrial Production, Pharmacopoeias, Life Time of Pharmaceutical Preparations and Ingredients. **Ref 1: Chapter 1 and 2, p 1-15** **Part-C:** Pharmaceutical Ingredients Production and Control, Pharmacopoeia Monographs, Impurities in Pharmaceutical Ingredients. **Ref 1: Chapter 18 (305-321)**	
Chapter 2: Part-A: Fundamentals of bases, Acids, solubility, Polarity, Partition and stereochemistry	**10 Hours**
Acids, Bases, pH and pKa, Buffers, Acid and base properties of drug substances , Distribution Between phases, Stereoisomers, Active Pharmaceutical Ingredient (API) - Fluoxetine, Atenolol, Morphine, Ibuprofen, Paracetamol, Hydrocortisone, Stability of drugs. **Ref -1, Chapter 3, 17-34** **Part-B**: **Methods of common impurity testing** a) Definition of Limit Test and b) Limit test for heavy metals (IP methd-A only), iron, lead, chloride, sulphate, water, ash and sulphated ash. Ref-2, Indian Pharmacopeia- volume-1)	
Chapter 3: Application of UV, IR optical rotation and HPLC in Quality Control of Pharmaceuticals	**10 Hours**
UV Visible spectroscopy: Recapitulation: Beers law, molar absorbance, specific absorbance, principle of spectrophotometry, method for quantitative analysis (absolute, relative method and calibration curve method), Test of Spectrophotometers (calibration of UV-Visible spectrophotometer): control over wavelength, Control over absorbance (tef-1: pp 116 to 118), Identification of Diazepam in Diazepam Tablets (Solid Preparation) by UV Spectrophotometry, Identification of Flupentixol Decanoate in Flupentixol Decanoate Injection (Liquid Preparation) by UV Spectrophotometry, Identification of Miconazole in Miconazole Nitrate Cream (Semi-Solid Preparation) by UV Spectrophotometry 9Ref-1 pp: 406 -410); Assay of Paracetamol in Paracetamol Tablets (Solid Preparation) by UV Spectrophotometry, Assay of Doxapram in Doxapram Hydrochloride Injection (Liquid Preparation) by UV Spectrophotometry (Ref-1: pp: 419-423) **IR Spectroscopy:** Basic principle of IR spectroscopy, functional group and IR absorption, Identification of aspirin (acetylsalicylic acid) in aspirin tablets (solid preparation) by IR spectrophotometry, Identification of fluoxetine in fluoxetine hydrochloride oral solution (liquid preparation) by IR spectrophotometry, Identification of mupirocin in mupirocin	

calcium nasal ointment (semi-solid preparation) by IR-spectrophotometry (Ref-1: pp 396 to 400).

HPLC: Principle of HPLC, Chromatogram and its characteristics, method of qualitative analysis by HPLC, method of quantitative analysis by HPLC (relative method and calibration curve method) Identification of fluoxetine in fluoxetine hydrochloride capsules (solid preparation) by LC, Identification of droperidol in droperidol injection by LC, (Ref-1: 401-406) Assay of Omeprazole in Gastro-Resistant Omeprazole Tablets (Solid Preparation) by LC, Assay of Fentanyl in Fentanyl Citrate Injection (Liquid Preparation) by LC, Assay of Hydrocortisone in Hydrocortisone Ointment (Semi-Solid Preparation) by LC (Ref-1: pp 411-419).

Optical Rotation: Definition of Optical and specific rotation. method of optical and specific rotation determination, Optical rotation for simvastatin according to Ph. Eur., (Ref-1: pp 335-339) specific rotation for glucose, sugar; Ref-2: Indian pharmacopeia 7 Ed. Vol-1 (137-138 and Vol-2 (397-398).

References:

1. Introduction to Pharmaceutical Analytical Chemistry, Stig Pedersen-Bjergaard et al., Wiley Publication, 2nd Edition, 2019.
2. Indian Pharmacopoeia, Indian Pharmacopoeia Commission, 7th Edition, Vol. 1, 2 & 3, 2014.