Module number	**12**
Course Title	**Pharmaceutical Analysis II**
Course Code	**Phar 3122**
Course EtCTS (Course hour)	**7 (189 hrs)**
Pre-requisite	**Pharmaceutical Analysis I**
Co-requisite	**none**
Course Description	The course deals with the applications of important instrumental analytical techniques such as spectro-chemical methods including UV- Visible, atomic absorption, flame spectroscopy, mass spectroscopy and nuclear magnetic resonance spectroscopy; chromatographic methods including Gas Chromatography and High Performance Liquid Chromatography in quality controls of pharmaceutical products. The course has 16 weeks of practical classes in which different instrumental analytical techniques will be studied as employed in the estimation of the constituents of drugs included in the national drug list
Course Objectives	After completing this course, students will be able to understand the instrumentation of different modern instrumental analytical techniques and their use in pharmaceutical and biochemical analysis. They will also able to propose suitable analytical technique for a sample, carry out analysis for different pharmaceuticals as well as handle, interpret and report data obtained from the analysis.
Supporting objectives	• Describe UV-Visible spectroscopy • Describe infrared spectroscopy • Describe fluorescence spectroscopy • Describe atomic spectroscopy • Describe mass spectroscopy • Identify different chromatographic techniques • Describe gas chromatography • Describe high performance liquid chromatography • Describe biological methods of analysis

Course Content

1. UV- Visible spectrophotometry …… 10 hrs
   - 1.1. Introduction
   - 1.2. Factors governing absorption of radiation in the UV/Visible region
     - 1.2.1. The concept of Chromophore and Auxochrome
     - 1.2.2. Absorption intensity shifts
     - 1.2.3. Effect of pH on absorption
     - 1.2.4. Conjugated dienes and Wood Ward and Fiesher's rule
   - 1.3. Instrumentation
     - 1.3.1. Radiation sources

1.3.2. Monochromators
1.3.3. Sampling cells and compartments
1.3.4. Detectors
1.3.5. Recording systems
1.3.6. Double and single beam instruments
1.4. Qualitative spectrophotometry
1.5. Quantitative spectrophotometry
1.5.1. Beer's law and its limitations
1.5.2. Spectrophotometric titrations
1.6. Analysis of binary mixtures
1.7. Differential Spectrophotometry 2 hrs
1.8. Derivative spectra
1.9. Colorimetry
1.9.1. General requirements for colored substances
1.9.2. Chemistry in colorimetry
1.10. Applications

2. Fluorescence spectrophotometry …… 7 hrs
2.1. Introduction
2.2. Instrumentation
2.3. Structural requirements of fluorescent compounds
2.4. Factors affecting fluorescence intensity
2.5. Applications in pharmaceutical analysis

3. Infrared Spectrophotometry ……
3.1. Introduction
3.2. Instrumentation
Dispersive, FTIR and NIR, Radiation sources, Monochromators, Photometer, Detectors, Recorders
3.3. Fundamental vibrations and factors affecting vibration frequency
3.4. Sample preparation
3.5. Scanning IR spectra. 5 hrs
3.6. Interpretation of the spectra
3.7. Applications
3.7.1. IR spectrophotometry as a fingerprint technique
3.7.2. Quantitative IR analysis
3.7.3. IR spectrophotometry in structure elucidation

4. Atomic spectrophotometry …….
4.1. Introduction 2 hrs
4.2. Types of atomic spectrophotometric techniques
4.2.1. Atomic absorption spectrophotometry (AAS)
4.2.2. Atomic emission spectrophotometry (AeS)

4.3. Instrumentation
4.4. Applications

5. Nephelometry and Turbidometry ……... 2 hrs
   5.1. Introduction
   5.2. Instrumentation
   5.3. Pharmaceutical applications
6. Introduction to chromatography ……. 2 hrs
   6.1. History and principles
   6.2. Classifications
   6.3. Definition of terminologies
7. Gas Chromatography (GC) …… 6 hrs
   7.1. Introduction
   7.2. Instrumentation
   7.3. Carrier gas cylinder, Injection port, Column and column oven, Detectors, Recorders and integrators
   7.4. Factors affecting choice of carrier gas
   7.5. Temperature Programming in GC
   7.6. Pyrolysis and derivatization in GC
   7.7. Qualitative and quantitative analysis by GC
8. High performance liquid chromatography (HPLC) …… 8 hrs
   8.1. Introduction and theory
   8.2. Instrumentation
   Pump, Injection system, Column, Detectors, Data system
   8.3. Stationary and mobile phases
   8.4. Structural factors governing rate of elution of compounds
   8.5. Evaluation of column performance
   8.6. Applications in:
   Identification, Quantitative analysis, Chiral separation
9. Mass Spectrometry ……. 5 hrs
   9.1. Introduction
   9.2. Instrumentation
   9.3. Molecular fragmentation patterns
   9.4. GC-MS and LC-MS
   9.5. Applications in pharmaceutical analysis
10. Nuclear magnetic resonance spectroscopy ……. 5 hrs
   10.1. Introduction to 1H NMR and 13C NMR spectroscopy
   10.2. Basic instrumentation.
   10.3. Chemical shifts.
   10.4. Shielding and deshielding effects.
   10.5. Factors influencing chemical shifts.

10.6. Peak area and proton counting
10.7. Important tips for interpreting NMR spectra.

11. Biological methods of analysis……. 3 hrs
11.1. Introduction
11.2. Microbiological assay
11.3. Pyrogen testing (in vivo & in vitro)
11.4. Microbial limit test
11.5. Sterility test
11.6. Preservative efficacy test

12. Introduction to herbal drugs quality control 2 hrs
12.1. Introduction
12.2. Methods of herbal drugs quality control
12.3. Challenges in standardization of herbal drugs

Total **5 8hrs**

Mode of Delivery

- Lecture: 58
- Tutorial: 10
- Seminars, assignments and Presentation: 10
- Practical/ Laboratory: 36
- Home study: 59
- Assessment: 10
- Visits to pharmaceutical firms and quality control laboratories: 6 hrs

Mode of Evaluation

- Seminar and assignments: 10%
- Laboratory written exams and report writing: 10%
- Practical exams: 15%
- Quizzes: 10%
- Final Exam: 30%
- Viva: 5%
- Quality control visit report: 10%

Text Book

Beckett, A.H. and Stenlake, J.B. Practical Phamaceutical Chemistry, Parts I & II, 4th edn., The Athlone Press, London, 1988.

Reference Books

Connors, K.A. Textbook of Pharmaceutical Analysis, 3rd edition., 1982

David G. Watson. Pharmaceutical Analysis, A Textbook for Pharmacy Students and Pharmaceutical Chemists, 2nd Edition, 2005, Elsevier.

Gary D. Christian; Analytical chemistry, 6th edition, John Wiley and Sons INC., USA, 2004

USP/NF (Latest edition). The United States Pharmacopoeial convention, Inc. Rockville, MD., USA

British Pharmacopoeia (Latest edition), Her Majesty stationery office, London.

David Harvey. Modern analytical chemistry. 1st ed, Mc Graw Hill, Boston, 2000.

Francis Rouessac and Annick Rouessac, Chemical Analysis, Modern instrumental methods and techniques, 2nd ed, John Wiley and Sons, LTD, England, 2007.

Satinder Ahuja and Michael W. Dong. Handbook of Pharmaceutical Analysis by HPLC. 1st ed, volume 6, Elsevier Academic Press, New York, 2005.