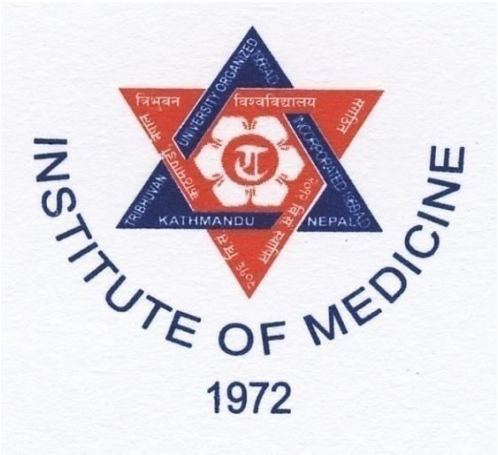
Curriculum

on

Bachelor in Pharmacy

(B. Pharm)



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INSTITUTE OF MEDICINE

NATIONAL CENTRE FOR HEALTH PROFESSIONS EDUCATION

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PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE II

Subject: Theory	Year: Third	Code: BP 603 A
Full Marks: 100	Total Teaching hours: 90	Credit hour: 6

Course Description: This course deals with the instrumental analysis, quality assurance and total quality management.

General objectives:

At the end of the course, the students will be able to

- **a.** Outline different commonly used analytical techniques use for drug analysis.
- **b.** Explain principle and application of different spectroscopic techniques.
- **c.** Demonstrate working and operation of different spectrophotometer.
- **d.** Explain principles of liquid and gas chromatography
- **e.** Discuss total quality management (TQM) principles
- **f.** Describe international standards and quality assurance theories and principles

Specific objectives:

Unit 1: UV and visible spectrophotometry: **[5Hrs]**

After the completion of the course, students will be able to

- **a** Discuss Electrotransitions, chromophores, spectral shifts, solvent effect
- **b** Derive Beer & Lambert's Law
- **c** Discuss deviations to Beer & Lambert's Law.
- **d** Describe Principle, Intrumentation and application of Single & double beam spectrophotometer.
- **e** Discuss advantages & disadvantages of UV/Vis Spectrophotometry
- **f** Discuss Single & multicomponent analysis by UV/Vis Spectrophotometry

Unit 2: Fluorimetry: [4 Hrs]

After the completion of the course, students will be able to

- **a** Discuss concepts of singlet, doublet and triplet electronic states
- **b** Describe factors affecting fluorescence and quenching
- **c** Describe Principle, Instrumentation, Advantages & disadvantages and pharmaceutical applications of Fluorimetry (with suitable examples)

Unit 3: Infrared (IR) spectrophotometry [5Hrs]

After the completion of the course, students will be able to

- **a** Discuss Fundamental modes of vibration
- **b** Explain Sample handling Infrared (IR) spectrophotometry
- **c** Explain Principle, Instrumentation, Applications and Spectral Interpretations of Infrared (IR) spectrophotometry
- **d** Discuss IR spectrum table

e Describe factors affecting vibrational frequency

Unit 4: Nuclear Magnetic Resonance Spectroscopy including ^{13}C NMR. [8Hrs]

After the completion of the course, students will be able to

a Discuss the working principle of NMR Spectroscopy

b Explain Instrumentation, Application and Spectral Interpretations of NMR Spectroscopy (^{1}H, ^{13}C and 2D-NMR)

c Discuss chemical shift scale and explain various factors affecting Chemical shift

d Discuss Shielding & Deshielding of proton,

e Discuss Types of ^{13}C-NMR

Unit 5: Mass Spectrometry [5Hrs]

After the completion of the course, students will be able to

a Discuss working Principle, Instrumentation and application of Mass spectrometry.

b Discuss different methods of ionization

c Discuss different types of Mass analysers.

d Discuss different rules of fragmentation in Mass spectrometry.

Unit 6: Flame Photometry [4Hrs]

After the completion of the course, students will be able to

Discuss Principle, Instrumentation, Advantages & disadvantages and pharmaceutical applications of Flame photometry (with suitable examples).

Unit 7: Emission Spectrometry (AES) [3Hrs]

After the completion of the course, students will be to

Discuss Principle, Instrumentation, Advantages & disadvantages and pharmaceutical applications of Emission Spectrometry (with suitable examples).

Unit 8: Atomic Absorption Spectroscopy (AAS) [4Hrs]

After the completion of the course, students will be able to

Discuss Principle, Instrumentation, Advantages & disadvantages and pharmaceutical applications of Atomic Absorption Spectroscopy (with suitable examples).

Unit 9: X-Ray Diffraction [4Hrs]

After the completion of the course, students will be to

Discuss Principle, Instrumentation, Advantages & disadvantages and pharmaceutical applications of X-Ray Diffraction (with suitable examples).

Unit 10: Radioimmunoassay (RIA)[3Hrs]

After the completion of the course, students will be able to

a Discuss Principle, Instrumentation, Advantages & disadvantages and pharmaceutical applications of Radioimmunoassay (with suitable examples).

b Discuss different technique of RIA

Unit 11: Chromatography: [9 Hrs]

After the completion of the course, students will be able to

- **a** Describe Paper chromatography and column chromatography.
- **b** Discuss the principle of separation, instrumentation and application of TLC, HPTLC, HPLC, GLC. (with suitable examples)

Unit 12: Pharmaceutical quality assurance

After the completion of the course, students will be able to

- **a** Discuss elements & concept of ISO, ISO 9001, ISO 14001**:**Overview, Elements, Benefits, Steps of Registration. [**5Hrs]**
- **b** Explain Total Quality Management (TQM): Concept of TQM, Definition, elements, philosophies [**4Hrs]**
- **c** Describe Quality Policy, Quality Circle, Quality Review, Quality Manual and Quality documentation. [**4Hrs]**
- **d** Discuss Approach to Certification, Application for registration, Regulatory control, [**4 Hrs]**
- **e** Explain Validation: Validation and Qualification, 4Qs, different approaches, scope of validation, Validation of analytical instruments. [**5 Hrs]**
- **f** Describe GMP manufacturing practices as per WHO Guidelines: Concept and components, Quality Assurance & Quality Control, Organization & personnel, Premises, Equipments & Raw materials, Complaints, Sanitation & Hygiene, Documentation – SOP, BMR, MFR, BFR, Quality documentation, Report & Distribution records. GLP (Good laboratory practices). C-GMP, ICH-PICS [**10Hrs]**
- **g** Discuss ISO Guide 17025 and quality audit**:** Concepts, elementsand importance. [**4Hrs]**

PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE II

Subject: Practical	Year: Third	Code: BP 603 B
Full Marks: 50	Total Teaching hours: 90	Credit hour: 2

At the end of the course, students will be able to:

1. Perform analysis of Pharmacopoeial compounds in bulk and in theirformulations (tablet/ capsules/ semisolids) by UV-Vis spectrophotometer
2. Perform IR spectroscopy of samples having different functional groups (-CO; -COOH; -COOR; NH_2, -NHR, -OH, etc.).
3. Prepare and standardise perchloric acid and sodium/potassium/lithium methoxide solutions; Estimation of some pharmacopeial products.
4. Perform Complexometric Titrations: Preparations and standardisation of EDTA solution, some exercise related to pharmcopeial assays of complexometric titrations.
5. Determine alcohol content in povidone iodine.

6. Perform Simultaneous estimation of multi-drug component containingformulations by UV spectrophotometry
7. Perform experiments involving separation of API from multiigredients, e.g Cotrimoxazole, Metronidazole-Diloxanoide furoate).
8. Perform estimation of riboflavin/quinine sulphate by fluorimetry
9. Identify some pharmaceutical products using chromatographic technique like TLC, HPLC.
10. Perform experiments based on Gas Chromatography
11. Perfrom assay of raw materials as per official monographs.
12. Perform estimation of Na^+, K^+, Ca^{2+} ions using flame photometry/AAS.
13. Perform in process and finished product quality control tests for tablets,capsules, parenterals and semisolid dosage forms

Reference books [Latest edition]

1. Conners K.A. A Textbook of Pharmaceutical Analysis. Wiley Inter-science.
2. Beckett A.H, StenlakeJ.B. Practical Pharmaceutical Chemistry, Part I and Part II (CBS Publishers, Delhi)
3. Kar A. Pharmaceutical Drug Analysis. New Age International Publishers.
4. Kemp W. Organic spectroscopy. Macmillan International Higher Education.
5. Sethi P.D. Quantitative analysis of drugs in pharmaceutical formulations. Unique Publishers
6. Basseter G.C, Silverstein RM. Spectrophotometric identification of organic compounds. Wiley, New York.
7. Skoog D. A, West D. M. Principles of Instrumental Analysis, (Saunders golden sunburst series).