



Code No. H-8070/PCI

**FACULTY OF PHARMACY**

**M. Pharmacy (Pharma Analysis) I - Semester (PCI) (Backlog) Examination, Dec. 2025**

**Subject: Advanced Pharmaceutical Analysis**

**Time: 3 Hours**

**Max. Marks: 75**

**Note: Answer any Five questions. All questions carry equal marks.**

**(5x15=75 Marks)**

1. (a) Classify and write the potential sources of elemental impurities. [5]  
(b) Explain the guidelines for reporting and control of elemental impurities in new drug products. [10]
2. (a) Describe the FDA/ICH guidelines for reporting levels of impurities in residual [10]  
(b) Write a short note on the qualification of degradation products. [5]
3. (a) Write the systematic approach to the stability evaluation of drug substances. [8]  
(b) Explain the influence of temperature, pH buffering species ionic strength, and dielectric constant on drug stability. [7]
4. (a) Explain various principles and testing procedures involved in degradant characterization [7]  
(b) Classify residual solvents by risk assessment and describe their limits. [8]
5. (a) Write about HPLC as a fingerprinting tool in stability testing of phytopharmaceuticals [10]  
(b) What are accelerated stability studies and how do you calculate the shelf life of drug products? [5]
6. Write about the following  
(i) ELISA [8]  
(ii) Fluorescence Immunoassay [7]
7. (a) Discuss the biological assay of the diphtheria vaccine. [8]  
(b) What are antitoxins? Give biological assay of Tetanus antitoxin. [7]
8. Write the principle, procedure and applications of PCR studies. [15]

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Code No: H-8072/PCI

**FACULTY OF PHARMACY**  
**M. Pharmacy(PCI) (Pharmaceutical Analysis) I - Semester (Backlog)**  
**Examination, December 2025**

**Subject: Food Analysis**

**Time: 3 Hours**

**Max. Marks: 75**

**Note: Answer any Five Questions.**

**(5 x 15 = 75 Marks)**

1. What is the importance Vit B series? Explain the microbial assay of vit B series.
2. Classify aminoacids and proteins. Explain the general methods for the analysis of aminoacids and proteins.
3. (a) How will you detect the adulteration in oil and fat?  
(b) Explain the analysis of preservatives and flavor enhancers. (9+6 Marks)
4. Write about Natural pigments and permitted synthetic pigments in food. Name the nonpermitted dyes used by industries. Add a note on the detection of the above.
5. Explain the role of preservatives, stabilizers and antioxidants in food with examples from each category. Add a note on their analysis.
6. Explain the chemical nature and analytical methods for milk, cheese and butter.
7. Describe the legislation regulation by BIS and Agmark for food products.
8. (a) Classify carbohydrates and write about general methods of analysis of food carbohydrates.  
(b) Explain the methods to determine organophosphorus and organochlorine pesticides in fruits and vegetables. (7+8 Marks)

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Code No.: H-8071/PCI

**FACULTY OF PHARMACY**

**M. Pharmacy (Pharma. Analysis) I - Semester (PCI) (Backlog) Examination, December 2025**

**Subject: Pharmaceutical Validation**

**Time: 3 Hours**

**Max. Marks: 75**

**Note: Answer any Five questions**

**(5 x 15 = 75 Marks)**

1. a) Define qualification and validation in the context of pharmaceutical manufacturing. How do these concepts differ?  
b) Explain about different phase of instrument qualification.
2. Explain the procedure for the following:  
a) Calibration of UV spectrophotometer  
b) Sampling methods for cleaning validation.
3. List out and explain the different method validation parameters according to ICH guidelines for analytical procedures.
4. Write about different steps involved in the calibration of analytical balance. Explain the qualification process for High-performance Liquid chromatography (HPLC) systems.
5. Discuss the validation process for pharmaceutical water systems. What are the critical parameters to consider, and how does compliance with regulations ensure the quality of water used in pharmaceutical manufacturing?
6. Write notes on the following:  
a) Digital significance of 21 CFR part II?  
b) Validation master plan.
7. a) Define intellectual property (IP) and its significance in today's economy. Write the mechanism for protecting intellectual property, focusing on patents, copyrights, and trademarks.  
b) Discuss the process of filing a patent application. What are the essential forms and guidelines that must be followed.
8. Explain the Following terms.  
(a) Patent Infringement and Technology Transfer.  
(b) Qualification of Glassware.

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Code No: G-13152/PCI

**FACULTY OF PHARMACY**

**M. Pharmacy (Pharmaceutical Analysis) I - Semester (PCI (Main & Backlog) Examination, June 2025**

**Sub: Pharmaceutical Validation**

**Time: 3Hrs**

**Marks:75**

**Note: Answer any 5 questions only. All questions carry equal marks.**

1. Explain the following (8+7 Marks)
  - a) Electronic Records
  - b) Objectives and advantages of validation
2. Explain the procedure for following (7+8 Marks)
  - a) Calibration of Analytical balance
  - b) Sampling methods for cleaning validation
3. List out and explain the analytical method validation parameters. (15 Marks)
4. Explain the various types of trademarks and don'ts in trademarks with Suitable examples. (10+5 Marks)
5. Write note on the following. (8+7 Marks)
  - a) Define and explain the types of process validation.
  - b) Different steps involved in the calibration of FTIR.
6. a) What are the different phases of water system validation?  
b) Explain the procedure to calibrate wavelength of UV instrument. (10+5 Marks)
7. a) What are the different parameters in HVAC to be examined?  
b) What is meant by revalidation and when to revalidate? (12+3 Marks)
8. Write note on the following (8+7 Marks)
  - a) Types of Patent applications
  - b) Validation master plan...

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Code No: G-13153/PCI

**FACULTY OF PHARMACY**  
**M. Pharmacy (Pharmaceutical Analysis) I – Semester (Main & Backlog) Examination,**  
**June 2025**  
**Subject: Food analysis**

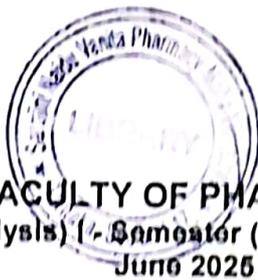
**Time: 3 Hours**

**Max. Marks: 75**

**Note: Answer any five questions. All questions carry equal marks.**

1. a) Differentiate dietary fibre from crude fibre.  
b) Add a note on the chemical nature and hydrogenation of fat and oil. (7+8 Marks)
2. Classify carbohydrates. What are the general methods for the analysis of carbohydrates?
3. Explain Natural pigments, permitted synthetic pigments and non-permitted synthetic pigments giving suitable examples. Add a note on their detection methods.
4. What are vitamins? Explain analytical methods for vitamins A, B and C.
5. Explain any two legislation regulations for food products.
6. a) Explain the methods to determine the organophosphorus pesticides in fruits and vegetables.  
b) How will you determine the Vit C content in food? (8+7 Marks)
7. a) Explain the analytical methods to detect methanol and ethanol content in wine and beer.  
b) What are the analytical methods for ice cream, milk powder and butter. (6+9 Marks)
8. a) What is the composition of cheese? What are the tests for cheese?  
b) Explain Kjeldahl method for the overall protein content in food. (8+7 Marks)

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Code No: F-13161/PCI

**FACULTY OF PHARMACY**

**M. Pharmacy (Pharma. Analysis) I - Semester (PCI) (Main & Backlog) Examination,  
June 2026**

**Subject: Advanced Pharmaceutical Analysis**

**Time: 3 Hours**

**Max Marks: 76**

**Note: Answer Any Five Questions. All Questions carry Equal Marks.**

1. (a) Examine the rationale behind controlling degradation products in new drug products. What are the implications of degradation products on the safety and efficacy of pharmaceuticals?  
(b) Discuss the process of reporting degradation product content in batches and how these products are specified and qualified.
2. (a) Discuss the classification of elemental impurities and the potential sources of elemental impurities in drug formulations.  
(b) Describe the FDA/ICH guidelines for reporting levels of impurities in residual solvents.
3. (a) Write the systematic approach to the stability evaluation of drug substances.  
(b) Explain the influence of temperature, pH buffering species ionic strength, and dielectric constant on drug stability.
4. (a) Discuss the specific stability guidelines for biological products as established by the ICH.  
(b) Write the unique challenges do biological products present in terms of stability and impurity profiling?
5. (a) Write about HPTLC as a fingerprinting tool in stability testing of phytopharmaceuticals.  
(b) Discuss the implications of environmental factors on the stability of phytopharmaceuticals.
6. Write about the following
  - (a) ELISA
  - (b) Fluorescence Immunoassay
7. (a) Discuss the biological tests used for the assessment of diphtheria vaccine.  
(b) Discuss the biological assays conducted for Rabies vaccine.
8. Discuss the principles and procedures of PCR (Polymerase Chain Reaction) in the quality control of biological products.

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Code No. G-13122/PCI

**FACULTY OF PHARMACY**

**M. Pharmacy (PCI) I – Semester (Main & Backlog) Examination, June 2025**

**Subject: Modern Pharmaceutical Analytical Techniques  
(Common to All)**

**Time: 3 Hours**

**Max. Marks: 75**

**Note: Answer any five questions. All questions carry equal marks.**

1. (a) Write Beer –Lambert's law and explain the deviations to it. (7 Marks)  
(b) Explain the instrumentation of FTIR. (8 Marks)
2. (a) Write principle involved in proton NMR spectroscopy. Discuss on chemical shift (7 Marks)  
(b) Explain the instrumentation of NMR with labelled schematic diagram. (8 Marks)
3. (a) Discuss about different ionization techniques of mass spectroscopy. (7 Marks)  
(b) Brief out the fragmentation patterns and rules of different organic compounds. (8 Marks)
4. (a) Write instrumentation details of HPLC with labelled schematic diagram. (10 Marks)  
(b) Differentiate between HPTLC and HPLC. (5 Marks)
5. (a) Explain about gel electrophoresis. (8 Marks)  
(b) What is X-ray crystallography? Write Brag's law. (7 Marks)
6. Write notes on  
(a) Sampling in IR spectroscopy  
(b) FT-NMR. (2 x 7.5 = 15 Marks)
7. Give informative note on  
(a) Flame emission spectroscopy  
(b) Gas chromatography (2 x 7.5 = 15 Marks)
8. (a) Explain the instrumentation of UV-Visible spectrophotometer. (10 Marks)  
(b) Write about any one X-ray crystallographic method. (5 Marks)

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