Code No. H-8060/PCI

# FACULTY OF PHARMACY

**M. Pharmacy (PCI) - Pharmaceutical Chemistry/Pharmaceutics/Pharmacology /Pharmaceutical Analysis/Ph.Quality Assurance**
**I - Semester (Backlog) Examination, December 2025**
**(Common paper for all Streams)**

**Subject: Modern Pharmaceutical Analytical Techniques**

**Time: 3 Hours** **Max. Marks: 75**

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

1. (a) State and Explain Beer- Lambert's law. Add a note on the deviations from Beer's law.
   (b) Explain the principle of flame photometry (7+8 Marks)
2. (a) Explain the sampling techniques in IR spectroscopy.
   (b) List and explain the IR detectors. (7+8 Marks)
3. (a) Define chemical shift. What are the factors affecting chemical shift?
   (b) Explain the spin-spin coupling in NMR spectroscopy with suitable example. (7+8 Marks)
4. What is the principle of MS? With a neat labelled diagram briefly explain the components of MS instrumentation. (15 Marks)
5. Explain the principle, instrumentation and application of capillary electrophoresis giving a neat labelled diagram. (15 Marks)
6. (a) Explain Bragg's equation and derive the equation.
   (b) List and explain the different **methods** used for X-ray diffraction studies. (7+8 Marks)
7. (a) What is the principles of Fluorescence? Add a note on the factors affecting fluorescence and quenchers in fluorescence.
   (b) What are the applications of AAS? (9+6 Marks)
8. (a) Explain the principle and instrumentation of HPLC.
   (b) List and explain any 3 GC detectors. (7+8 Marks)

******

OU - 1702 OU - 1702

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]

* * *

OU - 1702 OU - 1702

**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 organphosphorus and organochlorine pesticides in fruits and vegetables. (7+8 Marks)

******

OU - 1702 OU - 1702

**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.

******

OU - 1702 OU - 1702

**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)

******

OU - 1702 OU - 1702

**Code No: F-13151/PCI**

# FACULTY OF PHARMACY

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

**Subject: Advanced Pharmaceutical Analysis**

**Time: 3 Hours** **Max Marks: 75**

**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.

*********

OU - 1702 OU - 1702

**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 an 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 frutis 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)

******

OU - 1702 OU - 1702

**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...

******

OU - 1702 OU - 1702

**Code No: G-13014/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharma. Analysis) I - Semester (Backlog) Examination, December 2024**

**Subject: Advanced Pharmaceutical Analysis**

**Time: 3 Hours** **Max Marks: 75**

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

1. (a) Define impurities in pharmaceutical substances. Discuss the various classifications of impurities in drug substances and active pharmaceutical ingredients (APIs). (5)
   (b) Explain the ICH guidelines for the quantification and reporting of these impurities in new drug products? (10)

2. (a) Evaluate the significance of stability testing protocols in the pharmaceutical industry. What factors must be considered when selecting batches for stability testing? (7)
   (b) Discuss the importance of parameters such as container orientation, sampling frequency, and storage conditions in maintaining drug integrity. (8)

3. (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)

4. (a) Describe the accelerated stability testing and shelf-life calculation in the development and approval of pharmaceutical products? (10)
   (b) Discuss the different stability zones and their relevance to the testing process. (5)

5. (a) Explain the significance of impurity profiling and degradant characterization in the pharmaceutical industry. (5)
   (b) Describe different analytical techniques used in the characterization of degradants. (10)

6. (a) Write short notes on HPTLC fingerprinting in stability testing of phytopharmaceuticals. (8)
   (b) Discuss the regulatory requirements for stability testing of phytopharmaceuticals. (7)

7. (a) Write the procedures and principles of antivenom testing. (7)
   (b) Discuss the Biological assay methods for oxytocin. (8)

8. (a) Discuss the biological assay of Rabies vaccine. (7)
   (b) Write the different method used for the separation of bound and unbound drug in immunoassays. (8)

*********

OU - 1702 OU - 1702

**Code No: G-13019/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharmacy Practice) I - Semester (PCI) (Backlog) Examination, December 2024**

**Subject: Clinical Research**

**Time: 3 Hours** **Max.Marks:75**

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

1. (a) Write the ICH GCP guideline. [7]
   (b) Describe the INDA submission. [8]

2. (a) Write a note on BA-BE studies. [7]
   (b) Explain about the randomization techniques. [8]

3. (a) Write a note on pre-study visit and investigator meeting. [7]
   (b) Describe about the case report form and informed consent form. [8]

4. (a) Explain the essential documents for close out report. [7]
   (b) Write a note on master file preparation. [8]

5. (a) Write a note on SOPs for clinical trail. [7]
   (b) Describe the management of laboratory data and ADR data. [8]

6. (a) Explain in brief about the ethical issues in biomedical research. [7]
   (b) Write a note on types of research designs. [8]

7. (a) Describe the health outcome measures in clinical research. [7]
   (b) Explain the role and responsibility of sponsor and CRO. [8]

8. (a) Explain about the CRF tracking and corrections. [7]
   (b) Write a note on planning and execution of clinical trail. [8]

*****

OU - 1702 OU - 1702

**Code No: G-13015/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharm. Analysis) I – Semester (PCI) (Backlog) Examination, December 2024**

**Subject: Pharmaceutical Validation**

**Time: 3 Hours** **Max.Marks:75**

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

1. Explain the difference between qualification and validation, and explain about different phases of instrument qualification. [15]

2. Explain the procedure for the following:
   (a) Calibration of FTIR [8]
   (b) Sampling methods for cleaning validation. [7]

3. (a) List out and explain the analytical method validation parameters according to ICH guidelines. [10]
   (b) Explain the various types of trademarks and don'ts in trademarks with suitable examples. [5]

4. (a) Explain different steps involved in the calibration of analytical balance. [7]
   (b) Explain the procedure to calibrate UV spectrophotometers. [8]

5. (a) What are the different phases of water system validation? [7]
   (b) What are the different parameters in HVAC to be examined? [8]

6. Write notes on the following:
   (a) Digital significance of 21 CFR part II? [5]
   (b) Validation master plan. [10]

7. (a) Define and explain various Intellectual Property Rights. [5]
   (b) Write about the procedure of obtaining an International Patent. [10]

8. Explain the following terms.
   (a) User requirement specification [5]
   (b) Factory acceptance test [5]
   (c) Site acceptance test [5]

******

OU - 1702 OU - 1702

Code No: F-7239/PCI

# FACULTY OF PHARMACY

**M. Pharmacy I - Semester (PCI) (Common to All) (Main & Backlog) Examination, June 2024**

**Subject: Modern Pharmaceutical Analytical Techniques**

**Time: 3 Hours** **Max. Marks: 75**

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

1. (a) Explain different methods of single component and Multicomponent analysis of Pharmaceutical formulation by UV-Visible Spectroscopy. [9]
   (b) Explain the electronic transitions in UV spectroscopy. [6]

2. (a) Explain the molecular vibrations in IR. [8]
   (b) Write the sampling methods in IR spectroscopy. [7]

3. (a) Explain the principle of fluorescence. Add a note on quenching effect.
   (b) With a diagram explain the instrumentation for AAS. [8+7]

4. (a) Explain the principle and Instrumentation of NMR Spectroscopy. [8]
   (b) Write a note on spin-spin coupling and Applications of NMR [7]

5. (a) Classify the ionization techniques in MS. Explain any three methods in detail. [9]
   (b) Define Base peak, molecular ion peak and metastable ion. [6]

6. (a) Write the principle and instrumentation of flame photometry. [7]
   (b) Write notes on any two GC detectors with a neat labeled diagram. [8]

7. (a) Briefly explain the source of AA. [8]
   (b) List and explain the interferences. [7]

8. Discuss the principle, instrumentation working and application of [7+8]
   (a) Paper electrophoresis
   (b) Gel electrophoresis

*****

OU - 1702 OU - 1702

**Code No: F-7252/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharm. Analysis) I – Semester (PCI) (Main & Backlog) Examination, June 2024**

**Subject: Advanced pharmaceutical analysis**

**Time: 3 Hours** **Max.Marks:75**

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

1. (a) Define Impurity and give the classification of impurities in new drug substances. [5]
   (b) Explain the guidelines for reporting and control of elemental impurities in new drug products. [10]

2. Discuss accelerated stability studies and shelf-life calculation of drug products. [15]

3. (a) Discuss the FDA/ICH guidelines for reporting levels of impurities in residual. solvents. []
   (a) Write a short note on the qualification of degradation products. []

4. (a) How do you perform stability studies for drug products as per ICH guidelines? Explain. [9]
   (b) Explain the effect of temperature and pH on the stability of new drug formulations. [6]

5. (a) Describe different analytical techniques used in the characterization of degradants.[]
   (b) Write about ICH stability guidelines for biological products. []

6. (a) Write short notes on HPTLC fingerprinting in stability testing of phytopharmaceuticals. [10]
   (b) Give the regulatory requirements for stability testing of phytopharmaceuticals. [5]

7. Write the principle, procedure, and applications of radioimmunoassay. Write a short note on optical Immunoassay. [15]

8. (a) Discuss the biological assay of Rabies vaccine. [7]
   (b) Write the principle and procedure involved in the bioassay of the Diphtheria vaccine. [8]

******

OU - 1702 OU - 1702

**Code No: F-7253/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharma. Analysis) I – Semester (PCI) (Main & Backlog) Examination, June 2024**

**Subject: Pharmaceutical Validation**

**Time: 3 Hours** **Max.Marks:75**

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

1. (a) Define qualification and validation. Write about the design qualification and performance qualification phases of analytical equipment. [10]
   (b) Explain the calibration procedure of glassware in analytical work. [5]

2. (a) How do you qualify IR spectrophotometers? Explain. [10]
   (b) Write about FAT and SAT. [5]

3. (a) Describe the validation procedure for the HVAC system. [10]
   (b) Write about cleaning-in-place (CIP). [5]

4. Describe method validation parameters as per ICH guidelines for validation of new analytical procedures. [15]

5. (a) What is an intellectual property right? Explain about different types of IPR. [8]
   (b) Explain the criteria of the patentability of an invention and the steps in the patent application. [7]

6. (a) Explain the procedure involved in the qualification and calibration of HPLC. [10]
   (b) Write about the cleaning of facilities. [5]

7. (a) Explain the steps involved in the preparation of the validation Master Plan (VMP). [10]
   (b) Write a short note on the Digital significance of 21 CFR part II [5]

8. (a) Write about the international patenting requirement procedure. [8]
   (b) Write about PCT and WIPO [7]

******

OU - 1702 OU - 1702

**Code No: F-7254/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharmaceutical Analysis) I - Semester (PCI) (Main / Backlog) Examination, June 2024**

**Subject: Food Analysis**

**Time: 3 Hours** **Max. Marks: 75**

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

1. Classify carbohydrates. What are the general methods for the analysis of carbohydrates?

2. Explain the significance, principle and process for saponification value. Differentiate acid value from saponification value. Add a note on hydrogenation of fats and oils.

3. Classify vitamins. Explain methods for the analysis of vitamins A, B and C.

4. Explain in detail the food additives giving suitable examples from each category.

5. Explain Natural pigments, permitted synthetic pigments and non permitted synthetic pigments giving suitable examples. Add a note on their detection methods.

6. (a) What are the analytical methods to detect methanol and ethanol content in wine and beer.
   (b) What are the analytical methods to test the purity quality of ice cream, milk powder and butter. (6+9)

7. Explain any three legislation regulation for food products.

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)

*****

OU - 1702 OU - 1702

**Code No: E-12421/PCI**

# FACULTY OF PHARMACY

**M.Pharmacy I-Semester (PCI) (Common to all) (Backlog) Examination, November-2023**

**Subject: Modern Pharmaceutical Analytical Techniques**

**Time: 3 Hours** **Max. Marks: 75**

**Note: Answer any Five Questions. All Questions carry Equal marks.**

1. a) Explain the electronic transitions with suitable examples
   b) State and explain Beer- Lambert's law. Add a note on the deviations from Beer's law. (6+9)

2. a) Explain the sampling techniques in IR spectroscopy.
   b) What are the applications of IR spectroscopy (9+6)

3. a) What is the principles of flame photometrty? Explain the instrumentation.
   b) What are the factors affecting fluorescence? (9+6)

4. a) Explain chemical shift and the factors affecting chemical shift ?
   b) Draw a schematic NMR spectrum and explain splitting $\alpha$ signal intensity. (10+5)

5. With a neat labelled diagram, explain MS instrumentation. Draw MS spectrum for any two compounds $\alpha$ explain its peaks.

6. a) Classify the ionization techniques in MS. Explain any three methods in detail.
   b) Explain the fragmentation rules in MS. (9+6)

7. a) Explain HPLC instrumentation with a labelled diagram.
   b) Explain the factors affecting resolution & peak symmetry. (8+7)

8. a) Explain the principle and applications of capillary electrophoresis
   b) Classify the types of crystals and add a note on the applications of X-ray diffraction. (8+7)

*******

OU - 1702 OU - 1702

**Code No: E-12436/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharma. Analysis) I Semester (PCI) (Backlog) Examination, November 2023**

**Subject: Food Analysis**

**Time: 3 Hours** **Max. Marks: 75**

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

1. a) Define and classify Proteins [5]
   b) Explain various methods for determination of proteins. [10]

2. a) Explain various methods for determination of oil and fats. [7]
   b) Define vitamins explain any two methods for determination of Vitamin A [8]

3. Write about the following
   a) Analysis of preservatives [5]
   b) Flavor and flavor enhancers [5]
   c) Analysis of stabilizers [5]

4. a) Explain the Gerber method for determination of fat in milk [7]
   b) Define milk. Enlist and write identification tests for the different adulterants in milk. [8]

5. a) Explain BIS and AGMARK [8]
   b) Define Pesticides and how do you analyse organochloro pesticides. [7]

6. Define carbohydrates? Explain various methods for determination of carbohydrates. [15]

7. a) Explain the determination of Ethyl alcohol content in Beer. [8]
   b) Determination of salt content in butter by Volhard's method. [7]

8. a) Explain the changes in food carbohydrates during digestion, absorption and metabolism [10]
   b) Explain 2, 6 dichlro phenol indophenol method for determination of Vitamin C. [5]

*******

OU - 1702 OU - 1702

**Code No: E-12435/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Phar. Analysis) I Semester (PCI) (Backlog) Examination, November 2023**

**Subject: Pharmaceutical Validation**

**Time: 3 Hours** **Max. Marks: 75**

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

1. (a) Explain the terms qualification and validation. Write in detail about steps involved in qualification of analytical instruments. [10]
   (b) Explain the calibration of Electronic balances used in analytical work. [5]

2. (a) How do you qualify UV spectrophotometers? Explain. [10]
   (b) Write about FAT and SAT. [5]

3. Write short notes on
   (a) HAVC system validation [8]
   (b) Pharmaceutical water system validation [7]

4. Describe method validation parameters as per ICH guidelines for validation of new analytical procedures. [15]
5. (a) What is an intellectual property right? Explain about different types of IPR. [8]
   (b) Explain the criteria of the patentability of an invention and the steps in the patent application. [7]

6. (a) Explain the procedure involved in the qualification and calibration of HPLC. [10]
   (b) Write about the cleaning of facilities. [5]

7. (a) Explain the steps involved in the preparation of the validation Master Plan (VMP). [10]
   (b) Write a short note on the Digital significance of 21 CFR part II. [5]

8. (a) Write about the international patenting requirement procedure. [8]
   (b) Write about PCT and WIPO. [7]

*********

OU - 1702 OU - 1702

**Code No: E-12434/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharm. Analysis) I – Semester (PCI) (Backlog) Examination, November 2023**

**Subject: Advanced Pharmaceutical analysis**

**Time: 3 Hours** **Max. Marks: 75**

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

1. (a) Define Impurity and give the classification of impurities in new drug substances. [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 solvents. [10]
   (b) Write a short note on the qualification of degradation products. [5]

3. (a) Explain the factors affecting the stability of drug substances and drug products. [10]
   (b) How do you perform photostability of formulations? [5]

4. (a) Write about different analytical techniques used in the characterization of degradants. [10]
   (b) What is impurity profiling and give its importance in the testing of pharmaceutical products? [5]

5. (a) Write about HPTLC as finger printing 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
   (a) Radio immunoassay [8]
   (b) Optical Immunoassay [7]

7. (a) Describe the principle and procedure involved in the biological assay of oxytocin. [8]
   (b) What are antitoxins? Give biological assay of Diptheria antitoxin. [7]

8. (a) Discuss the different polymerase chain reaction studies for gene expression. [8]
   (b) Explain the different steps involved in the production of antibodies. [7]

*********

OU - 1702 OU - 1702

**Code No: E-12297/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy I Semester (PCI) (Common to all) (Main & Backlog) Examination, May 2023**

**Subject: Modern Pharmaceutical Analytical Techniques**

**Time: 3 Hours** **Max. Marks: 75**

**Note: Answer any Five Questions. All Questions carry Equal marks.**

1. a) With a neat labelled diagram explain UV/Visible instrumentation.
   b) What are the criteia in the solvent selection for UV spectroscopy? Give examples for solvents. What is meant by solvent effect? (9+6)

2. a) Explain the Principle, advantages and instrumentation of FTIR with a neat labelled diagram.
   b) Explain the molecular vibrations in IR spectroscopy. (10+5)

3. a) Explain the principle of fluorescence. Add a note on quenching effect
   b) With a diagram explain the instrumentation for AAS. (8+7)

4. a) Explain the principle of proton NMR spectroscopy.
   b) Explain the spin-spin coupling in NMR spectroscopy with suitable example. (7+8)

5. a) Explain the principle of mass spectroscopy.
   b) Explain any two mass analysers used in MS in detail. (7+8)

6. a) Explain GC instrumentation with a labelled diagram.
   b) Explain the applications of XRD technique. (9+6)

7. a) Explain the instrumentation & working of HPLC. (8+7)
   b) Explain the factors affecting resolution & Peak symmetry.

8. Define and classify the electrophoretic techniques. Explain the principle and applications of gel electrophoresis. (15)

*******

OU - 1702 OU - 1702

**Code No: E-12310/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharm. Analysis) I – Semester (PCI) (Main & Backlog) Examination, May 2022**

**Subject: Advanced Pharmaceutical analysis**

**Time: 3 Hours** **Max. Marks: 75**

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

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

1. (a) Explain the guidelines for reporting and control of degradation products in new drug products. [10]
   (b) Give the classification of residual solvents and their limits in drug substances and drug products. [5]

2. Describe accelerated stability studies and shelf life calculation of drug products. [15]

3. Write about
   (a) Control of elemental impurities [8]
   (b) Potential sources of elemental impurities [7]

4. (a) How do you perform stability studies for drug products as per ICH guidelines? Explain. [9]
   (b) Explain the affect of temperature and pH on stability of new drug formulations. [6]

5. (a) Describe different analytical techniques used in characterization of degradants. [10]
   (b) What is impurity profiling and give its importance in testing of pharmaceutical products. [5]

6. (a) Write short notes on HPTLC finger printing in stability testing of phytopharmaceuticals. [10]
   (b) Give the regulatory requirements for stability testing of phytopharmaceuticals. [5]

7. (a) Write the principle and procedure involved in radioimmunoassay. [8]
   (b) Discuss different polymerase chain reaction studies for gene expression. [7]

8. (a) Discuss the biological assay Rabies vaccine. [7]
   (b) Write the principle and procedure involved in the bioassay of Diptheria vaccine.[8]

*********

OU - 1702 OU - 1702

**Code: E12311/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Phar. Analysis) I – Semester (PCI) (Main & Backlog) Examination, May 2023**

**Subject: Pharmaceutical Validation**

**Time: 3 Hours** **Max. Marks: 75**

**Note: Answer any five questions. All questions carry equal marks. (5 x 15 = 75 Marks)**

1. (a) Define qualification and explain the different phases of the qualification process of analytical equipment. [10]
   (b) Write short notes on the re-validation process. [5]

2. (a) Describe in detail the cleaning validation. [10]
   (b) Write about validation master validation. [5]

3. Describe the method validation parameters for a new analytical method as per USB guidelines. [15]

4. Write about the following [3 x 5 = 15]
   (a) Revalidation
   (b) Factory acceptance test and site acceptance test.
   (c) Calibration of pH meter.

5. (a) Explain the Qualification procedure of the FTIR instrument. [8]
   (b) Write about PCT and WIPO [7]

6. (a) What is a Patent? Explain the procedure for filing an application for a patent in India. [9]
   (b) What is a patent infringement and its scope? [6]

7. (a) Explain the procedure involved in the qualification and calibration of HPLC. [10]
   (b) Write a short note on the Digital significance of 21 CFR part II. [5]

8. (a) Explain about HVAC validation process in detail [10]
   (b) Write the role of Intellectual property in the pharmaceutical industry. [5]

*********

OU - 1702 OU - 1702

**Code No: E-12312/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharma. Analysis) I - Semester (PCI) (Main & Backlog) Examination, May 2023**

**Subject: Food Analysis**

**Time: 3 Hours** **Max. Marks: 75**

**Note: Answer any Five Questions. All Questions carry Equal marks.**

1. a) Define and classify carbohydrates. [5]
   b) Explain various methods for determination of carbohydrates. [10]

2. a) Give any two methods for determination of Vitamin $B_{12}$ [10]
   b) Explain 2, 6 dichlro phenol indophenol method for determination of Vitamin C. [5]

3. Write about the following
   a) Analysis of antioxidants [7]
   b) Detection of permitted and non-permitted dyes [8]

4. Explain the following methods for determination of fat in milk [15]
   a) Gerber method
   b) Rose- Gottlieb method

5. Explain the various methods for determination of Organo phosphorus and organo chlorine pesticides in fruits and vegetables. [15]

6. a) List out the quality control tests for fat and oils.Explain the principle, procedure and significance of saponification value. [8]
   b) Explain Kjeldahl method for determination of protein in ice creams [7]

7. Explain the determination of ethanol and methanol in wine samples. [15]

8. Write about the following
   a) BIS and AGMARK
   b) Explain any two methods for determination of Proteins.

*******

OU - 1702 OU - 1702

**Code No. E-12084/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Common to All) I - Semester (PCI) (Backlog) Examination, December 2022**

**Subject: Modern Pharmaceutical Analytical Techniques**

**Time: 3 Hours** **Max. Marks: 75**

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

1 (a) With a neat labelled diagram explain UV/Visible spectrophotometer instrumentation.
(b) What are the applications of UV spectroscopy?

2 (a) Explain the molecular vibrations in IR.
(b) Write the sampling methods in IR spectroscopy.

3 (a) Explain the principle of fluorescence.
(b) With a diagram explain the instrumentation for flame photometry.

4 (a) Explain the principle of proton NMR spectroscopy.
(b) Explain the following in NMR spectroscopy: Shielding and deshielding, chemical shift.

5 (a) Explain the principle of mass spectroscopy.
(b) Explain any two mass analysers used in MS in detail.

6 (a) Explain GC instrumentation with a labelled diagram. Add a note on the different types of GC columns.
(b) List and explain any 2 GC detectors.

7 (a) Explain Braggs equation and derive the equation.
(b) Explain the principle and types of Paper electrophoresis.

8 (a) Explain the principle and applications of ELISA?
(b) Explain the principle and applications of capillary electrophoresis.

* * *

OU - 1702 CJ - 1702

**Code No. E-12097/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharmaceutical Analysis) I Semester (PCI) (Backlog) Examination, December 2022**

**Subject: Advanced Pharmaceutical Analysis**

**Time: 3 Hours** **Max. Marks: 75**

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

1 (a) Define Impurity and give the classification of impurities in new drug substances.
(b) Explain the guidelines for reporting and control of elemental impurities in new drug products.

2 Describe accelerated stability studies and shelf life calculation of drug products.

3 Explain the factors affecting stability of drug substance and drug products. How do you perform photo stability of formulations?

4 Describe different analytical techniques used in characterization of degradants. What is impurity profiling and give its importance in testing of pharmaceutical products.

5 Write a short notes on HPTL finger printing in stability testing of phytopharmaceuticals. Give the regulatory requirements for stability testing of phytopharmaceuticals.

6 Write about the following:
(a) Radio Immunoassay
(b) Optical Immunoassay

7 Describe the principle and procedure involved in the biological assay of oxytocin. What are antitoxins? Give biological assay of Tetanus antitoxin.

8 Write the principle, procedure and applications of PCR studies.

* * *

OU - 1702 OU - 1702

**Code No. E-12099/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharmaceutical Analysis) I - Semester (PCI) (Backlog) Examination, December 2022**

**Subject: Food Analysis**

**Time: 3 Hours** **Max. Marks: 75**

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

1 (a) Explain determination of Ash and mineral constituents in food materials.
(b) Define and classify proteins. Explain kjeldahl method for determination of overall protein concentration in food samples.

2 (a) Discuss the principle, procedure and significance of acid value.
(b) Explain any two methods for determination of Vitamin B.

3 Write about the following
(a) Analysis of thickening and jelling agents.
(b) Method of detection of permitted and non permitted dyes.

4 Explain the following methods for determination of fat in milk.
(a) Gerber method
(b) Rose-Gottlieb method

5 (a) Explain the multi residue gas chromatographic method for determination of synthetic pyrethroid in fruits and vegetables.
(b) Write a note on BIS and AGMARK.

6 Write about the following
(a) Determination of titrable acidity in dried milk.
(b) Analysis of preservatives

7 Explain different methods for determination of Vitamin $B_{12}$.

8 Explain the determination of ethanol and methanol in wine samples.

* * *

OU - 1702 OU - 1702

**Code No. E-12098/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharmaceutical Analysis) I Semester (PCI) (Backlog) Examination, December 2022**

**Subject: Pharmaceutical Validation**

**Time: 3 Hours** **Max. Marks: 75**

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

1 (a) Define qualification and explain the different phases of qualification process of analytical equipments.
(b) Write short notes on re-validation process.

2 (a) Describe Pharmaceutical water system validation.
(b) Write about cleaning-in-place (CIP)

3 (a) Describe the following method validation parameters for a new analytical method as per ICH guidelines.
(b) Linearity, Precision, Accuracy and Specificity.

4 Write about the following
(a) Validation master plan
(b) Factory acceptance test and site acceptance test
(c) Calibration of analytical balance.

5 Explain the procedure to calibrate wavelength and optical scale of spectrophotometer. Write about PCT and WIPO.

6 (a) What is Patent? Explain the procedure for filing an application for patent in India.
(b) What is Patent infringement and its scope?

7 (a) Explain about cleaning validation process in detail.
(b) Write short note on Digital significance of 21 CFR part II.

8 (a) Explain the procedure involved in qualification and calibration of HPLC.
(b) Write the role of Intellectual property in pharmaceutical industry.

* * *

OU - 1702 OU - 1702

**Code No. D-8261/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy I - Semester (Common to All) (PCI) (Main & Backlog) Examination, May 2022**

**Subject: Modern Pharmaceutical Analytical Techniques**

**Time: 3 Hours** **Max. Marks: 75**

**Note: Answer any five questions.** **(5 x 15 = 75 Marks)**

1 (a) State and explain Beer-Lambert's Law. Add a note on the deviations from Beer's law.
(b) Explain the concept of chromophore, auxochrome and bathochromic shift with suitable examples.

2 (a) Explain the instrumentation of FTIR with a neat labelled diagram. Add a note on the advantages of FTIR.
(b) Explain the mplecular vibrations in IR.

3 (a) What is the principle AAS? Explain the instrumentation.
(b) List the differences between AAS and flame photometry.

4 What is the significance of chemical shift? What are the factors affecting chemical shift? Name the internal standard and justify its selection as internal standard in NMR spectroscopy.

5 What is the principle of Mass Spectrometry? With a neat labelled diagram briefly explain the components of MS instrumentation.

6 (a) Classify the ionization techniques in MS. Explain any three methods in detail.
(b) Define Base peak, molecular ion peak and metastable ion.

7 (a) Explain the principle of X-ray diffraction.
(b) Explain HPLC instrumentation with a labelled diagram.

8 (a) Explain the experimental set up required for gel electrophoresis.
(b) Describe the principle and applications of RIA.

* * *

OU - 1702 OU - 1702

**Code No. D-8276/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharmaceutical Analysis) I-Semester (PCI) (Main & Backlog) Examination, May 2022**

**Subject: Food Analysis**

**Time: 3 Hours** **Max. Marks: 75**

**Note: Answer any five questions.** **(5 x 15 = 75 Marks)**

1 Define carbohydrates? Explain various methods for determination of carbohydrates.

2 (a) List out the quality control tests for fats and oils. Explain the principle, procedure and significance of saponification value.
(b) Explain any two methods for determination of vitamin A.

3 Write about the following.
(a) Analysis of preservatives.
(b) Analysis of different flavors and flavor enhancers.

4 (a) Explain the Gerber method for analysis of fat in milk.
(b) Explain Kjedahl method for determination of protein in ice creams.

5 Explain various methods for determination of organophosphorus and organochlorine pesticides in fruits and vegetables.

6 (a) Give any two methods for determination of Vitamin $B_{12}$.
(b) Explain 2, 6 dichlro phenol indophenol method for determination of Vitamin C.

7 Write about the following
(a) BIS and AGMARK
(b) Determination of salt content in butter by Volhard's method.

8 (a) Explain the Karl fischer method for determination of moisture in proteins.
(b) Explain the determination of Ethyl alcohol content in Beer.

* * *

OU - 1702 OU - 1702

**Code No. D-8275/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharmaceutical Analysis) I-Semester (PCI) (Main & Backlog) Examination, May 2022**

**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. Write about design qualification and performance qualification phases of analytical equipment.
(b) Explain the calibration procedure of glassware used in analytical work.

2 (a) How do you qualify UV spectrophotometers? Explain.
(b) Write short note on re-validation process.

3 Write short notes on
(a) Cleaning validation
(b) Pharmaceutical water system validation

4 Describe method validation parameters as per ICH guidelines for validation of new analytical procedures.

5 (a) Describe qualification procedure of HPLC instrument.
(b) Explain the criteria of patentability of an invention and steps in patent application.

6 (a) Explain the procedure involved in qualification and calibration of FTIR.
(b) Write about factory acceptance test and site acceptance test.

7 (a) Explain the steps involved in preparation of Validation Master Plan (VMP)
(b) Write short note on Digital significance of 21 CFR part II.

8 (a) What is an intellectual property right? Explain about different types of IPR.
(b) Discuss the rights and responsibilities of patentee.

* * *

OU - 1702 OU - 1702

**Code No. D-8274/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharmaceutical Analysis) I-Semester (PCI) (Main & Backlog) Examination, May 2022**

**Subject: Advanced Pharmaceutical Analysis**

**Time: 3 Hours** **Max. Marks: 75**

**Note: Answer any five questions.** **(5 x 15 = 75 Marks)**

1 Explain the guidelines for reporting and control of degradation products in new drug products. Give the classification of residual solvents and their limits in drug substances and drug products.

2 Describe the FDA/ICH guidelines for reporting levels of impurities in residual solvents. Write a short note on qualification of degradation products.

3 Write about
(a) Control of elemental impurities
(b) Potential sources of elemental impurities.

4 Write about different analytical techniques used in characterization of degradants. What is impurity profiling and give its importance in testing of pharmaceutical products.

5 Write about HPTLC as finger printing tool in stability testing of phytopharmaceuticals. What are accelerated stability studies and how do you calculate shelf life of drug products.

6 Write the principle, procedure and applications of radioimmunoassay. Write short note on optical Immunoassay.

7 Discuss the biological assay of diphtheria vaccine. Write the principle and procedure involved in bioassay of Human anti haemophilic vaccine.

8 Discuss the different polymerase chain reaction studies for gene expression. Explain the different steps involved in production of antibodies.

* * *

OU - 1702 OU - 1702

**Code No. D8001/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy I Semester (PCI) (Suppl) Examination, December 2021**
**(COMMON TO ALL)**

**Subject: Modern Pharmaceutical Analytical Techniques**

**Time: 2 Hours** **Max. Marks: 75**

**Note: Answer any three questions. All questions carry equal marks.**
**(3 x 25 = 75 Marks)**

1 (a) State and explain Beer-Lambert's law. Add a note on the deviations from Beer's law.
(b) Explain the electronic transitions in UV spectroscopy.

2 (a) Explain the principle and instrumentation of FTIR with a neat labelled diagram.
(b) Explain the named advantages of FTIR.
(c) What are the major differences between Dispersive instruments and FTIR?

3 (a) What is the principle of Fluorescence? Explain the radiative and non radiative pathways of relaxation.
(b) Add a note on the factors affecting fluorescence.

4 (a) Explain NMR instrumentation with a diagram.
(b) Briefly explain shielding and deshielding with suitable example.

5 (a) What is the principle of MS? With a neat labelled diagram briefly explain the components of MS instrumentation.

6 (a) Classify the ionization techniques in MS. Explain any three methods in detail.
(b) Define Base Peak, molecular ion peak and metastable ion.

7 (a) Explain GC instrumentation with a labelled diagram.
(b) What are the applications of HPLC?

8 (a) Explain the experimental set up required for capillary electrophoresis.
(b) Describe the principle and application of ELISA.

****

OU - 1702 OU - 1702

**Code No. D8015/PCI**

# FACULTY OF PHARMACY

**M.Pharmacy (Pharmaceutical Analysis) I Semester (PCI) (Suppl) Examination, December 2021**

**Subject: Pharmaceutical Validation**

**Time: 2 Hours** **Max. Marks: 75**

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

**(3 x 25 = 75 Marks)**

1 a) Define qualification and explain the different phases of qualification process of analytical equipment.
b) Write short notes on re-validation process.

2 Write about the following:
a) Validation master plan
b) Factory acceptance test and site acceptance test.
c) Calibration of analytical balance.

3 a) Describe validation procedure for HVAC system.
b) Write about cleaning-in-place (CIP).

4 Describe the method validation parameters for a new analytical method as per ICH Guidelines.

5 a) What is an intellectual property right? Explain about different types of IPR.
b) Discuss the rights and responsibilities of patentee.

6 a) What is a Patent? Explain the procedure for filing an application for patent in India.
b) What is patent infringement and its scope?

7 a) Explain the procedure involved in qualification and calibration of HPLC.
b) Write short note on Digital significance of 21 CFR part II?

8 a) Describe in detail about cleaning validation process.
b) Write the role of intellectual property in pharmaceutical industry?

****

OU - 1702 OU - 1702

**Code No. D8014/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharmaceutical Analysis) I - Semester (PCI)(Suppl.)**

**Examination, December 2021**

**Subject: Advanced Pharmaceutical Analysis**

**Time: 2 Hours** **Max. Marks: 75**

**Note: Answer any three questions. All questions carry equal marks.**
**(3 x 25 = 75 Marks)**

1 a) Define Impurity and give the classification of impurities in new drug substances
b) Explain the guidelines for reporting and control of degradation products in new drug products.

2 a) Classify elemental impurities and write about control of elemental impurities.
b) Explain about potential sources of elemental impurities in pharmaceutical products.

3 a) How do you perform stability studies for drug products as per ICH guidelines? Explain.
b) How do you perform photo stability of formulations?

4 a) Describe different analytical techniques used in characterization of degradants.
b) Write about ICH stability guidelines for biological products.

5 a) Write about HPTLC as finger printing tool in stability testing of phytopharmaceuticals.
b) What are accelerated stability studies and how do you calculate shelf life of drug products.

6 Write about the following
a) Enzyme immunoassay
b) Optical Immunoassay

7 a) Discuss the biological assay of diphtheria vaccine
b) What are antitoxins? Give biological assay of Tetanus antitoxin.

8. Write the principle, procedure and applications of PCR studies.

*******

OU - 1702 OU - 1702

**Code No. D 8016/PCl**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharmaceutical Analysis) I-Semester (PCl) (Suppl.)**

**Examination, December 2021**

**Subject: Food Analysis**

**Time: 2 Hours** **Max. Marks: 75**

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

**(3 x 25 = 75 Marks)**

1 a) Explain determination of Ash and mineral constituents in food materials.
b) Define and classify proteins. Explain Kjeldahl method for determination of overall protein concentration in food Samples.

2 a) Discuss the principle, procedure and significance of acid value.
b) Explain any two methods for determination of Vitamin $B_1$

3 Write about the following
a) Analysis of thickening and jelling agents
b) Method of detection of permitted and non permitted dyes.

4 Explain the following methods for determination of fat in milk.
a) Gerber method
b) Rose-Gottlieb method

5 a) Explain the multi residue gas chromatographic method for determination Of synthetic pyrethroid in fruits and vegetables.
b) Write a note on BIS and AGMARK.

6 Write about the following
a) Determination of titrable acidity in dried milk
b) Analysis of preservatives

7 Explain different methods for determination of Vitamin $B_{12}$.

8 Explain the determination of ethanol and methanol in wine samples.

*******

OU - 1702 OU - 1702

**Code No. 12115/PCI**

**FACULTY OF PHARMACY**
**M.Pharmacy I Semester (PCI) (Main & Backlog) Examination, July 2021**
**(COMMON TO ALL)**

**Subject: Modern Pharmaceutical Analytical Techniques**

**Time: 2 Hours** **Max. Marks: 75**

**Note: Answer any three from the following questions.** **(3 x 25 = 75 Marks)**

1 (a) With a neat labelled diagram explain UV/Visible instrumentation.
(b) Briefly explain the electronic transitions with examples.

2 (a) Explain the molecular vibrations in IR.
(b) Write the sampling methods in IR spectroscopy.

3 (a) Explain the principle of flame photometry.
(b) With a diagram explain the instrumentation for flame photometry.
(c) List some metals that can be analysed by flame photometry.

4 (a) Explain the principle of proton NMR spectroscopy.
(b) What is the significance of chemical shift? What are the factors affecting chemical shift?
(c) What is the internal standard used in NMR spectroscopy? Why it is selected as internal standard?

5 (a) List and explain the steps in MS.
(b) What are the mass analysers used in MS? Explain any two in detail.

6 (a) Explain HPLC instrumentation with a labelled diagram.
(b) List and explain any 2 GC detectors.

7 (a) Explain Bragg's equation and derive the equation.
(b) Explain the principle and the materials required for Paper electrophoresis.

8 (a) Explain the principle and types of RIA?
(b) Briefly explain Zone electrophoresis and Moving boundary electrophoresis.

****

OU - 1702 OU - 1702

**Code No. 12145/PCl**

**FACULTY OF PHARMACY**
**M.Pharmacy (Pharmaceutical Analysis) I Semester (PCl) (Main & Backlog) Examination, July 2021**

**Subject: Pharmaceutical Validation**

**Time: 2 Hours** **Max. Marks: 75**

**Note: Answer any three from the following questions.** **(3 x 25 = 75 Marks)**

1 a) Define qualification and validation. Write about design qualification and performance qualification phases of analytical equipment.
b) Explain the calibration procedure of glassware used in analytical work.

2 a) How do you qualify UV spectrophotometers? Explain.
b) Write short note on re-validation process.

3 Write short notes on
a) Cleaning validation
b) Pharmaceutical water system validation.

4 Describe method validation parameters as per ICH guidelines for validation of new analytical procedures.

5 a) What is an intellectual property right? Explain about different types of IPR?
b) Explain the criteria of patentability of an invention and steps in patent application.

6 a) Explain the procedure involved in qualification and calibration of FTIR.
b) Write about factory acceptance test and site acceptance test?

7 a) Explain the steps involved in preparation of validation master plan (VMP).
b) Write short note on digital significance of 21 CFR part II?

8 a) Write about international patenting requirement procedure?
b) Write about PCT and WIPO.

****

OU - 1702 OU - 1702

**Code No. 12144/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharmaceutical Analysis) I-Semester (PCI)(Main & Backlog)**

**Examination, July 2021**

**Subject : Advanced Pharmaceutical Analysis**

**Time: 2 Hours** **Max. Marks: 75**

**Note: Answer any Three Questions.** **(3 x 25 = 75 Marks)**

1 a) Explain the guidelines for reporting and control of elemental impurities in new drug products.
   b) Give the classification of residual solvents and their limits in drug substances and drug products.

2 a) Describe the FDA/ICH guidelines for reporting levels of impurities in residual solvents.
   b) Write short note on qualification of degradation products.

3 a) Explain the factors affecting stability of drug substance and drug products.
   b) How do you perform photo stability of formulations?

4 a) Describe different analytical techniques used in characterization of degradants.
   b) What is impurity profiling and give its importance in testing of pharmaceutical products.

5 a) Write about HPLC as finger printing tool in stability testing of Phytopharmaceuticals.
   b) What are accelerated stability studies and how do you calculate shelf life of drug products.

6 Write about the following
   a) Radio immunoassay
   b) Fluro Immunoassay

7 a) Describe the principle and procedure involved in the biological assay of oxytocin
   b) Write the principle and procedure involved in bioassay of Human anti haemophilic vaccine

8 a) Discuss different polymerase chain reaction studies for gene expression.
   b) Explain the different steps involved in production of antibodies.

*******

OU - 1702 OU - 1702

**Code No. 12146/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharmaceutical Analysis) I-Semester (PCI) (Main & Backlog)**

**Examination, August2021**

**Subject : Food Analysis**

**Time: 2 Hours** **Max. Marks: 75**

**Note: Answer any Three Questions.** **(3 x 25 = 75 Marks)**

1 Define carbohydrates? Explain various methods for determination of carbohydrates.

2 a) List out the quality control tests for fats and oils. Explain the principle, procedure and significance of acid value
b) Explain any two methods for determination of vitamin C

3 Write about the following
a) Analysis of preservatives
b) Analysis of different flavors and flavor enhancers.

4 a) Explain the Gerber method for analysis of fat in milk.
b) Explain Kjeldahl method for determination of protein in ice creams.

5 Explain various methods for determination of organophosphorus and organochlorine pesticides in fruits and vegetables.

6 a) Give any two methods for determination of Vitamin $B_{12}$.
b) Explain any one method for determination of Vitamin A.

7 Write about the following
a) BIS and AGMARK
b) Determination of salt content in butter by Volhard's method.

8 a) Explain the Karl fischer method for determination of moisture in proteins.
b) Explain the determination of Ethyl alcohol content in Beer.

*******

OU - 1702, OU - 1702

**Code No. 6360/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharma. Analysis) I-Semester (PCI) (Suppl.) Examination, November 2020**

**Subject: Food Analysis**

**Time: 2 Hours** **Max. Marks: 75**

**Note: Answer any Three questions.** **(3 x25=75 Marks)**

1 Explain briefly the various qualitative and quantitative methods used for analyzing food carbohydrates.

2 (a) Write the different means used for classifying amino acids with appropriate examples.

(b) Explain the procedure, principle and significance for determining peroxide value and unsaponifiable matter in fats and oils.

3 (a) Define the following chemically with one structural example
i) Carbohydrate ii) Proteins iii) Amino acids
iv) Lipids v) fats/oils

(b) What are the vitamins? Explain the principle and significance for the microbiological methods used for the determination of spoilage and / or adulterants in fats and oils.

4 List out the spoilage products adulterants of fats and oils. Explain any five methods used for the determination of spoilage and/or adulterants in fats and oils.

5 Enlist any five food additives along with their uses and limits. Write the procedure and principle of any one method

6 Explain the various analytical methods employed for assuring the quality of ice creams.

7 (a) Explain the various methods used for the determination of pesticide residues in fruits and vegetables.
(b) Write briefly about USFDA regulation of food products.

8 (a) Describe the various test used to analyze the purity of wines.
(b) Explain the test which is conducted to analyze non-permitted dyes in food products.

*********

OU-1702 OU-1702

**Code No: 6359/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharmaceutical Analysis) I-Semester (PCI) (Suppl.)**

**Examination, November 2020**

**Subject : Pharmaceutical Validation**

**Time: 2 Hours** **Max. Marks: 75**

**Note: Answer any Three questions.** **(3 x 25 = 75 Marks)**

1. Explain the following
   a) Types of patent applications
   b) Objectives and advantages of validation

2 Explain the procedure for following
   a) Calibration of Volumetric glassware
   b) Sampling methods for cleaning validation

3. List out and explain the analytical method validation parameters.

4. Explain the various types of trademarks and don'ts in trademarks with suitable examples

5. Write note on the following.
   a) Define and explain the types of process validation
   b) Different steps involved in the calibration of HPLC

6. What are the different phases of water system validation?

7. What are the different parameters in HVAC to be examined?

8. Write note on the following
   a) Clean in place
   b) Validation master plan.

*******

OU - 1702 OU - 1702

**CODE NO: 6102/PCI**

# FACULTY OF PHARMACY

## M. Pharmacy I – Semester (Main & Backlog) Examination, January 2020
## (Common Paper for all Except Pharmacy Practice)

### Subject : Modern Pharmaceutical Analytical Techniques

**Time: 3 Hours** **Max. Marks: 75**

**Note:** Answer any Five Questions. All Questions Carry Equal Marks.

1. (a) State and explain Beer- Lambert's law. Add a note on the deviations from Beer's law. 8
   (b) Explain solvents and the selection criteria for UV/Visible spectroscopy. 4
   (c) What is solvent shift? 3

2. (a) Explain the principle and instrumentation of FTIR with a neat labelled diagram. 8
   (b) Explain about the sampling techniques and applications of FR spectroscopy 7

3. (a) What is the principle of Fluorescence? Explain the radiative and non radiative pathways of relaxation. 7
   (b) Add a note on the factors affecting fluorescence and quenchers in fluorescence. 6
   (c) What are the criteria for a molecule to exhibit the phenomena of fluorescence 2

4. (a) Explain the principle of proton NMR spectroscopy. 5
   (b) What is the significance of chemical shift. What are the factors affecting chemical shift ? 6
   (c) Explain about spin-spin crippling and it's importance in NMR 4

5. (a) Classify the ionization techniques in MS. Explain any three methods in detail. 12
   (b) Differentiate between Base peak and molecular ion peak. 3

6. (a) Explain HPLC instrumentation. 10
   (b) What are the applications of HPLC? 5

7. (a) Explain Braggs equation and derive the equation. 8
   (b) What is the principle involved in rotating crystal technique? 7

8. Explain the principle, working and applications of
   (a) Capillary electrophoresis $7^{1/2}$
   (b) Gel electrophoresis $7^{1/2}$

*******

OU - 1702 OU - 1702

**Code No: 6131/PCI**

# FACULTY OF PHARMACY

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

**February 2019**

**Subject: Advanced Pharmaceutical analysis**

**Time: 3 hours** **Max. Marks: 75**

**Note: Answer any five Questions. All Questions carry Equal Marks**

1 a) Explain the guidelines for reporting and control of degradation products in new drug products. 10
b) Explain the classifications of residual solvents and their limits in substances and drug products. 5

2 a) Describe the FDA/ICH guidelines for reporting levels of impurities in residual solvents. 10
b) Write short note on qualification of degradation products. 5

3 Write about :
a) Control of elemental impurities 8
b) Potential sources of elemental impurities. 7

4 a) Write about different analytical techniques used in characterization of degradants. 10
b) What is impurity profiling and give its importance in testing of pharmaceutical products. 5

5 a) Write about HPTLC as finger printing tool in stability testing of phytopharmaceuticals. 10
b) What are accelerated stability studies and how do you calculate shelf life of drug products. 5

6 a) Write the principle and procedure and applications of radioimmunoassay. 10
b) Write short note on optical Immunoassay. 5

7 a) Discuss the biological assay of diphtheria vaccine. 7
b) Write the principle and procedure involved in bioassay of Human anti haemophilic vaccine. 8

8 a) Discuss the different polymerase chain reaction studies for gene expression. 8
b) Explain the different steps involved in production of antibodies. 7

**********

OU - 1702 OU - 1702

**Code No: 6133/PCI**

# FACULTY OF PHARMACY

## M. Pharmacy (Pharma Analysis) I-Semester (PCI) (Main & Backlog) Examination, January 2020

### Subject : Food Analysis

**Time: 3Hours** **Max. Marks: 75**

**Note:** Answer Any Five Questions. All Questions Carry Equal marks

1. Classify proteins with examples. Describe the process of digestion. Absorption and metabolism of proteins and amino acids. 5+10

2 a) What are dietary fibers and crude fibers? Write their application and methods employed for analyzing them 2+8
   b) What are vitamins? Classify them with suitable examples 1+4

3. a) Explain the process of digestion and absorption of carbohydrates and proteins/amino acids. 5+5
   b) Explain the various process used for refining of fats and oils. 5

4. What are fats and oils chemically? Explain the various methods used for the analysis of fats and oils 1+14

5. a) Explain about occurrence and characteristic properties of natural pigments. 5
   b) Explain the various methods used for the detection of natural dyes. 10

6. Explain the various analytical methods employed for assuring the quality of butter. 15

7. a) Explain any three legislation regulations of food products. 12
   b) What are the effects of pest and insects on food. 3

8. a) Describe the various tests used to analyze the purity of beer. 10
   b) Explain the test which is conducted to analyze the presence of pesticides in milk products. 5

*******

OU - 1702 OU - 1702

**Code No.6132/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharmaceutical Analysis) I-Semester (PCI) (Main & Backlog) Examination, January 2020**

**Subject: Pharmaceutical Validation**

**Time: 3 Hours** **Max. Marks: 75**

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

1 Explain the following terms. 5+5+5
(a) User requirement specification
(b) Factory acceptance test
(c) Site acceptance test

2 Write note on the following
(a) Calibration of FTIR. (7)
(b) Cleaning in place (8)

3 Define IPR. Explain the criteria of patentability of an invention and describe the steps involved in patent application. (1+7+7)

4 Explain the difference between qualification, calibration, validation and explain about instrument qualification. (5+10)

5 Write note on the following.
(a) What are the different types of water used in pharmaceutical industry?
(b) Different steps involved in the calibration of HPLC instrument. (7+8)

6 (a) Discuss about pharmaceutical water system validation.
(b) Explain the procedure to calibrate wavelength of UV instrument. (10+5)

7 (a) Describe the Method Validation parameters for new Analytical method.
(b) What is meant by revalidation and when to revalidate? (12+3)

8 Write note on the following
(a) Types of process validation.
(b) Validation master plan. (8+7)

*********

OU - 1702 OU - 1702

**Code No. 13303/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Common paper for all Specialization) I-Semester (PCI) (Suppl.) Examination, August 2019**

**Subject : Modern Pharmaceutical Analytical Techniques**

**Time: 3 Hours** **Max. Marks: 75**

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

1 a) Write Beer-Lambert's law and derive the expression 5

b) Mention the different methods of quantitative analysis by uv-visible spectroscopy. Explain any one method in detail. 10

2. a) Explain the interpretation procedure of IR spectra of different organic compounds in detail. With examples of schematic IR spectra.

b) What is fluorescence? Write the factors affecting fluorescence. 5

3. a) What is chemical shift? Write the factors influencing chemical shift? 8

b) Write a note on FT-NMR 7

4. a) Explain the instrumentations and working of mass spectrometer with schematic diagram. 8

b) Write the fragmentation patterns of different organic compounds observed in mass spectroscopy. With the help of schematic mass spectra of a few compounds 7

5. Describe the components and working procedure of HPLC with a neat labeled block diagram. 15

6. a) Write the principle, instrumentation and working of zone electrophoresis. 8

b) Write the principle and theory of X-ray diffraction study using Brag's law 7

7. a) Write the principle and instrumentation of flame photometry 7

b) Write notes on any two GC detectors 8

8. Explain the principle, equipment, procedure, advantages and applications of IR Spectrophotometer 15

*******

OU - 1702 OU - 1702

**Code No: 13318/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharmaceutical Analysis) I – Semester(PCI) (Supple.) Examination, August 2019**

**Subject: Food Analysis**

**Time: 3hrs** **Max Marks: 75**

**Note: Answer any five questions, all questions carry equal marks**

1. Enlist the general methods for analyzing proteins and amino acids. Explain any three of them with suitable examples.

2. a) Enlist the factors responsible of fats and oils. Explain any three methods used for measuring the spoilage of fats and oils.
   b) Classify lipids with structural examples.

3. a) Explain the general methods of identifying and estimating natural and artificial stabilizers.
   b) Describe any two methods used for detecting natural dyes as coloring agents in food stuffs along with suitable examples.

4. a) Describe the various tests to analyze the purity of wines.
   b) Explain the test which is conducted to analyze the presence of bacteria in ice creams.

5. Give examples of organophosphorous and organochlorine pesticides. Explain the methods employed for analyzing them in mangoes.

6. a) Explain the process of digestion, absorption and metabolism of proteins.
   b) Define chemically fats and oils along with structural examples. Describe the various methods employed for refining fats and oils.

7. a) Describe the role of various legislations available for regulating food products.
   b) What is vinegar chemically? Describe the variable methods employed for analyzing the purity of vinegar.

8. (a) Explain the role of TLC and HPLC in the analysis of carbohydrates along with an appropriate example.
   (b) Distinguish between intense sweeteners and bulk sweeteners with examples. Describe any two tests used for the detection of saccharin in foods and beverages.

**********

OU - 1702 OU - 1702

**Code No. 13317 / PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharmaceutical Analysis) I – Semester (PCI) (Suppl.) Examination,**

**August 2019**

**Subject: Pharmaceutical Validation**

**Time: 3 Hours** **Max.Marks: 75**

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

1 Explain the following terms:
   a) User requirement specification 5
   b) Factory acceptance test 5
   c) Site acceptance test. 5

2 Write note on the following:
   a) Calibration of volumetric glassware 7
   b) Cleaning in place 8

3 Define IPR. Explain the criteria of patentability of an invention and describe the steps involved in patent application. 1+7+7

4 Explain the difference between qualification, calibration, validation and explain about instrument qualification. 5+10

5 Write note on the following:
   a) Different types of waters used in pharmaceutical industry. 7
   b) Different steps involved in the calibration of HPLC instrument. 8

6 a) Discuss about pharmaceutical water system validation. 10
   b) Explain the procedure to calibrate wavelength of UV instrument. 5

7 a) Describe the method validation parameters for new analytical method. 12
   b) What is meant by revalidation and when to revalidate? 3

8 Write note on the following:
   a) Types of process validation 8
   b) Validation master plan. 7

****

OU - 1702 OU - 1702

**CODE NO: 13147/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Common Paper for all Specialization) I – Semester**

**(Main & Backlog) Examination, January 2019**

**Subject : Modern Pharmaceutical Analytical Techniques**

**Time: 3 Hours** **Max. Marks: 75**

**Note:** Answer any Five Questions. All Questions Carry Equal Marks.

1) a) With a neat labeled diagram explain UV/Visible instrumentation. 8

b) Briefly explain the electronic transitions with examples 8

2) a) Explain the factors affecting vibrational frequencies in IR. 8

(b) Write the sampling methods in IR spectroscopy. 7

3 (a) Briefly explain the source of AAS. 8

(b) List and explain the interferences. 5

(c) List some metals that can be analysed by AAS. 2

4 (a) Explain NMR instrumentation. 8

(b) Briefly explain spin-spin coupling with a suitable example. 7

5 (a) What is the principle of MS. With a neat labelled diagram briefly explain the components of MS instrumentation. 8

(b) Explain Quadrupole and time of flight analysers in detail. 7

6. (a) What are the column efficiency parameters? 7

(b) List and explain any 2 GC detectors. 8

7. Explain the principle and application of capillary electophoresis. Give a labelled diagram to indicate the components of the instrument.

8 (a) Discuss the principle, instrumentation working and application of

a. Paper electrophoresis

b. Gel electrophoresis 7+8

*******

OU - 1702 OU - 1702

**Code No: 13162/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharmaceutical Analysis) I – Semester (PCI) (Main & Backlog) Examination, February 2019**

**Subject: Food Analysis**

**Time: 3 Hours** **Max. Marks: 75**

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

1. a) Enlist the various methods available for quantitatively analyzing food carbohydrates. Write the procedure, principle and advantages/disadvantages of any three of them. 1+9
   b) Describe briefly the various pathways involved in protein metabolism. 5

2 a) Explain the various methods employed for the determination of adulterants in fats and oils. 10
   b) Describe briefly about hydrogenation of vegetable oils. 5

3. a) Why methyl paraben is used in food stuffs. Explain the various qualitative and quantitative methods employed for identifying methyl paraben in food stuffs. 1+9
   b) Give example of permitted and non permitted synthetic dyes that can be used as coloring agents in food stuffs. Explain any one method used to detect non-permissible dyes in foods? 5

4. a) List down the various adulterant and contaminants of milk. Explain how freezing point depression (along with the procedure) determination is useful for identification of milk adulterants). 2+6
   b) Write the procedure, principle and significance of Gerber test and Babcock test with respect to analysis of milk. 7

5. a) Why pesticides are used in agriculture? Write down the side effects of using them with suitable examples. 10
   b) Explain briefly about BIS and AGMARK. 5

6. a) Describe the methods employed for the detection and estimation of antioxidants in fat/oils and food products. 10
   b) Describe the principle involved in the microbiological assay of vitamin B series. 5

7. Classify food carbohydrates with examples. Explain the process of digestion, absorption and metabolism of food carbohydrates. 3+12

8. a) Write down the composition of cheese. Describe the test carried out for the analysis of cheese. 2+10
   b) What are lipids? Write the qualitative tests used for the identification of lipids. 1+2

**********

OU - 1702 OU - 1702

**Code No. 13161 / PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharmaceutical Analysis) I-Semester (PCI) (Main & Backlog)**

**Examination, February 2019**

**Subject: Pharmaceutical Validation**

**Time: 3 Hours** **Max.Marks: 75**

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

1 Explain the following:
   a) Define and explain various Intellectual Property Rights. 5
   b) Write about procedure of obtaining an International Patent. 10

2 Explain the procedure for following:
   a) Calibration of FTIR 5
   b) Sampling methods for cleaning validation. 10

3 List out and explain the analytical method validation parameters. 15

4 Explain the various types of trademarks and don'ts in trademarks with suitable examples. 10+5

5 Write note on the following:
   a) Define and explain the types of process validation 8
   b) Different steps involved in the calibration of analytical balance. 7

6 a) What are the different phases of water system validation? 10
   b) Explain the procedure to calibrate wavelength of UV instrument. 5

7 a) What are the different parameters in HVAC to be examined? 12
   b) What is meant by revalidation and when to revalidate? 3

8 Write note on the following:
   a) Electronic records 5
   b) Validation master plan. 10

****

OU - 1702 OU - 1702

**Code No. 13160 / PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Phar.Analysi.) I – Semester (PCI) (Main & Backlog) Examination,**

**January 2019**

**Subject: Advanced Pharmaceutical Analysis**

**Time: 3 Hours** **Max.Marks: 75**

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

| | | | |
|---|---|---|---|
| 1 | a) | Define Impurity and give the classification of impurities in new drug substances. | 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 solvents. | 10 |
| | b) | Write short note on qualification of degradation products. | 5 |
| 3 | a) | Explain the factors affecting stability of drug substance and drug products. | 10 |
| | b) | How do you perform photo stability of formulations? | 5 |
| 4 | a) | Write about different analytical techniques used in characterization of degradants. | 10 |
| | b) | What is impurity profiling and give its importance in testing of pharmaceutical products. | 5 |
| 5 | a) | Write about HPTLC as finger printing tool in stability testing of phytopharma ceuticals. | 10 |
| | b) | What are accelerated stability studies and how do you calculate shelf life of drug products. | 5 |
| 6 | Write about the following | | |
| | a) | Enzyme immunoassay | 8 |
| | b) | Optical Immunoassay | 7 |
| 7 | a) | Describe the principle and procedure involved in the biological assay of oxytocin. | 8 |
| | b) | What are antitoxins? Give biological assay of Tetanus antitoxin. | 7 |
| 8 | a) | Discuss the different polymerase chain reaction studies for gene expression. | 8 |
| | b) | Explain the different steps involved in production of antibodies. | 7 |

****

OU - 1702 OU - 1702

Code No. 1289/PCI

# FACULTY OF PHARMACY

## M. Pharmacy (Common to All) I-Semester (PCI) (Suppl.) Examination,

## August 2018

**Subject: Modern Pharmaceutical Analytical Techniques**

**Time: 3 Hours** **Max. Marks: 75**

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

1 (a) Discuss the instrumentation of double beam UV visible spectrophotometer with a neat labeled diagram. (10)
(b) What is Isobestic point? Explain with a labeled UV spectrum giving tow examples. (5)

2 (a) Compare the instrumentation and working a dispersive and foruier transform IR spectrometers. Write the advantages and disadvantages of the two techniques. (10)
(b) Draw a schematic IR spectrum for any one compound and indicate the absorption wave number regions for any four functional groups in the compound. (5)

3 (a) Explain
(i) Chemical shift and factors influencing chemical shift. (6)
(ii) Spin-spin coupling and coupling constant. (6)
(b) Draw a schematic HNMR spectrum for any one compound and explain the following:
(i) Chemical shift values (ii) Nature of protons (iii) Number of protons (3)

4 (a) Discuss the theory and principle of mass spectroscopy and explain the instrumentation and working of mass spectrometer with a neat labeled diagram. (10)
(b) What is fragmentation? Explain the following by taking a simple example
(i) Fragmentation peaks (ii) Molecular ion peak (iii) Base peak (5)

5 (a) Discuss the theory of HPLC. Describe the instrumentation and working of HPLC with a neat labelled diagram. (10)
(b) Draw a schematic HPLC chromatomgram and explain
(i) Retention time (ii) Resolution (iii) Peak Asymmetry (5)

6 (a) Discuss the theory and principle of electrophoresis. Explain the method of capillary electrophoresis and its applications with examples. (12)
(b) What is isoelectric focusing? (3)

7 (a) Discuss the theory and principle of Gas chromatography. Explain the instrumentation and working of Gas chromatography and explain various stationary and mobile phases used in GC. (11)
(b) How non voralile compounds can be analysed by GC. Explain the technique with few examples? (4)

8 Write a note on :
(a) Flame emission spectroscopy (6)
(b) Instrumentation and application of Florescence spectroscopy (9)

OU-1702 OU-1702

**Code No. 1302/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharma. Analysis) I-Semester (PCI) (Supple.) Examination, August 2018**

**Subject: Advanced Pharmaceutical Analysis**

**Time: 3 Hours** **Max. Marks: 75**

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

1 (a) Define impurity and write classification of impurities in drug substances with examples. (5)
(b) Describe analytical procedures for quantification of impurities in drug products As per ICH guidelines and mention their threshold limits. (10)

2 (a) Classify and write the potential sources of elemental impurities. (5)
(b) Describe instrumentation and analytical procedures for analysis of carbon, hydrogen, nitrogen and sulphur impurities. (10)

3 (a) Write the systematic approach to 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 Write an account on WHO and ICH guidelines for stability testing. (15)

5 (a) Explain the role of analytical instruments (HPTLC & HPLC) in interaction and complexity studies of phytopharmaceuticals. (10)
(b) Write a note on stability testing protocols for herbal drugs. (5)

6 (a) Define bioassay. Describe the principle and method involved in bioassay of any one biological product. (8)
(b) What are antitoxins? Give biological assay of tetanus antitoxin. (7)

7 (a) Describe basic principles of radio immune assay. Enumerate its applications and limitations. (10)
(b) Describe the production of antibodies. (5)

8 (a) Write an account on Impurity profiling and degradation product characterization studies for gene regulation. (10)
(b) Classify residual solvents by risk assessment and describe their limits. (5)

*****

OU - 1702 OU - 1792

# FACULTY OF PHARMACY

**M. Pharmacy (Pharma. Analysis) I-Semester (PCI) (Supp.) Examination, August 2018**

**Subject: Pharmaceutical Validation**

**Time: 3 Hours** **Max. Marks: 75**

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

1 (a) Define qualification and explain the different phases of qualification process of analytical equipments. 10
(b) Write short notes on re-validation process. 5

2 Write about the following 3x5=15
(a) Validation master plan.
(b) Factory acceptance test and site acceptance test.
(c) Calibration of analytical balance.

3 (a) Describe validation procedure for HVAC system. 10
(b) Write about cleaning-in-place (CIP). 5

4 Describe the method validation parameters for a new analytical method as per ICH guidelines. 15

5 (a) What is an intellectual property right? Explain about different types of IPR. 8
(b) Discuss the rights and responsibilities of patentee. 7

6 (a) What is a Patent? Explain the procedure for filing an application for patent in India. 9
(b) What is patent infringement and its scope. 6

7 (a) Explain the procedure involved in qualification and calibration of HPLC 10
(b) Write short note on Digital significance of 21 CFR part II. 5

8 (a) Describe in detail about cleaning validation process. 10
(b) Write about preventive maintenance. 5

*****

OU - 1702 OU - 1702

**Code No. 1304/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharma. Analysis) I-Semester (PCI) (Supple.) Examination, August 2018**

**Subject: Food Analysis**

**Time: 3 Hours** **Max. Marks: 75**

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

1 (a) Explain determination of Ash and mineral constituents in food materials. (8)
(b) Define and classify proteins. Explain Kjeldahl method for determination of overall protein concentration in food Samples. (7)

2 (a) Discuss the principle, procedure and significance of acid value. (7)
(b) Explain any two methods for determination of Vitamin $B_1$ (8)

3 Write about the following
(a) Analysis of thickening and jelling agents. (7)
(b) Method of detection of permitted and non permitted dyes. (8)

4 Explain the following methods for determination of fat in milk. (15)
(a) Gerber method
(b) Rose- Gottlieb method

5 (a) Explain the multi residue gas chromatographic method for determination of synthetic pyrethroid in fruits and vegetables. (8)
(b) Write a note on BIS and AGMARK. (7)

6 Write about the following.
(a) Determination of titrable acidity in dried milk. (8)
(b) Analysis of preservatives (7)

7 Explain different methods for determination of Vitamin $B_{12}$ (15)

8 Explain the determination of ethanol and methanol in wine samples. (15)

****

OU - 1702 OU - 1702

**Code No. 1147/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Common to All) I-Semester (PCI) (Main) Examination,**
**February 2018**

**Subject: Modern Pharmaceutical Analytical Techniques.**

**Time: 3 Hours** **Max. Marks: 75**

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

1 (a) Derive the expression for Beer-Lambert law and explain the deviations with examples. (9)
(b) Explain the solvent effect with examples. (3)
(c) Discuss the principle and functions of monochromators in UV spectrophotometer. (3)

2 (a) Draw a schematic IR spectrum for any one compound and indicate the absorption wave numbers regions for any four functional groups in the compound. (5)
(b) Explain various kinds of IR vibrational modes and their energy levels. (5)
(c) Explain the sampling methods for liquids and solid samples for taking IR spectra. (5)

3 (a) Explain the principle and instrumentation of NMR spectroscopy. (10)
(b) Draw a schematic HNMR spectrum for any one simple compound and explain the following:
(i) Chemical shift values (ii) Nature of protons (ii Number of protons (5)

4 (a ) Explain about the ionization techniques - electron impact, chemical ionization, FAB and MALDI and their advantages and disadvantages. (12)
(b) What are isotopic peaks and how are they identified? What is the importance of isotopic peaks? (3)

5 (a) Discuss the theory of HPLC. Describe the instrumentation and working of HPLC with the help of a neat labeled diagram. (10)
(b) Draw a schematic HPLC chromatogram and explain
(i) Resolution (ii) Tailing (iii) Peak (5)

6 **(a)** Discuss the theory and principle of electrophoresis. Explain the method of gel electrophoresis and its applications with examples. (12)
b) What is isoelectric focusing? (3)

7 **(a)** Discuss about various types of detectors used in gas chromatography. (11)
(b) Explain about moving boundary electrophoresis with required labeled diagram. (4)

8 Write a note on:
(a) Emission spectroscopy (6)
(b) Instrumentation and application of fluorescence spectroscopy (9)

*******

CU-1702 CU-1702

**Code No. 1152/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharma. Analysis) I-Semester (PCI) (Main) Examination, February 2018**

**Subject: Pharmaceutical Validation**

**Time: 3 Hours** **Max. Marks: 75**

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

| | | |
|---|---|---|
| 1 | (a) Define qualification and validation. Write about design qualification and performance qualification phases of analytical equipment. | 10 |
| | (b) Explain the calibration procedure of glassware used in analytical work. | 5 |
| 2 | (a) How do you qualify UV spectrophotometers? Explain. | 10 |
| | (b) Write short note on re-validation process. | 5 |
| 3 | Write short notes on | |
| | (a) Cleaning validation | 8 |
| | (b) Pharmaceutical water system validation | 7 |
| 4 | Explain the ICH guidelines for validation of new analytical procedures. | 15 |
| 5 | (a) What is an intellectual property right? Explain about different types of IPR. | 8 |
| | (b) Discuss about violation of IPR and penalties. | 7 |
| 6 | (a) Write about international patenting requirement procedure. | 8 |
| | (b) Write about the role of Intellectual Property in Pharmaceutical Industry. Give few recent examples. | 7 |
| 7 | (a) Explain the procedure involved in qualification and calibration of FTIR. | 10 |
| | (b) Write about factory acceptance test and site acceptance test. | 5 |
| 8 | (a) Explain the steps involved in preparation of validation Master Plan (VMP). | 10 |
| | (b) Write short note on Digital significance of 21 CFR part II. | 5 |

*****

OU - 1702 OU - 1702

Code No. 1151/PCI

# FACULTY OF PHARMACY

**M. Pharmacy (Pharma. Analysis) I-Semester (PCI) (Main) Examination, February 2018**

**Subject: Advanced Pharmaceutical Analysis**

**Time: 3 Hours** **Max. Marks: 75**

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

1 (a) Explain in-detail about impurity profiling of new drug product. (10)
(b) Write classification and identification of elemental impurities. (5)

2 (a) Explain briefly protocol adopted for stability testing of drugs. (8)
(b) Describe briefly accelerated stability studies and determination of shelf-life. (7)

3 (a) Explain various principles and testing procedures involved in degradant characterization. (8)
(b) Describe ICH stability guidelines for biological products. (7)

4 (a) Write an account on requirements for stability testing of phytopharmaceuticals. (7)
(b) Describe the principle and methods involved in HPLC finger printing with suitable examples. (8)

5 (a) Mention different types of tetanus vaccine. Explain bioassay of adsorbed tetanus vaccine. (8)
(b) Describe the principle and procedure involved in bioassay of any one biological product. (7)

6 (a) Describe the principle, instrumentation and applications of radio immune assay. (8)
(b) Describe procedures for separation of bound and unbound drug during immunoassay. (7)

7 (a) Write an account on elemental impurities and their determination. (10)
(b) Explain basic principle and applications of PCR studies. (5)

8 (a) Write classification, potential sources, control and identification of residual solvent impurities. (10)
(b) Describe the production of antibodies. (5)

*****

OU - 1702 OU - 1702

**Code No. 1153/PCI**

# FACULTY OF PHARMACY

**M. Pharmacy (Pharma. Analysis) I-Semester (PCI) (Main) Examination, February 2018**

**Subject: Food Analysis**

**Time: 3 Hours** **Max. Marks: 75**

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

1 Define carbohydrates? Explain various methods for determination of carbohydrates. (15)

2 (a) List out the quality control tests for fats and oils. Explain the principle, procedure and significance of saponification value. (7)
(b) Explain any two methods for determination of vitamin A. (8)

3 Write about the following.
(a) Analysis of preservatives. (8)
(b) Analysis of different flavors and flavor enhancers. (7)

4 (a) Explain the Gerber method for analysis of fat in milk. (7)
(b) Explain Kjeldahl method for determination of protein in ice creams. (8)

5 Explain various methods for determination of organophosphorus and organochlorine pesticides in fruits and vegetables. (15)

6 (a) Give any two methods for determination of Vitamin $B_{12}$. (10)
(b) Explain 2, 6 dichlro phenol indophenol method for determination of Vitamin C. (5)

7 Write about the following
(a) BIS and AGMARK. (8)
(b) Determination of salt content in butter by Volhard's method. (7)

8 (a) Explain the Karl fischer method for determination of moisture in proteins. (7)
(b) Explain the determination of Ethyl alcohol content in Beer. (8)

*****

OU - 1702 OU - 1702