Code. No.M5082413

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**M.Pharmacy (Pharmaceutical Analysis) I Semester (PCI) (Supple) Examination July/August 2024**

**Subject: Pharmaceutical Validation**

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

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

| Q.No. | Question | Marks | CO | BL |
|---|---|---|---|---|
| 1 | a) Write about factory acceptance test and site acceptance test.<br>b) Write about validation master validation. | 8<br>7 | 1<br>1 | 1<br>1 |
| 2 | a) Explain the procedure involved in qualification and calibration of GC.<br>b) Explain the steps involved in the calibration of analytical balance. | 8<br>7 | 2<br>2 | 3<br>3 |
| 3 | a) Explain about cleaning validation process in detail.<br>b) Elaborate on parameters in HVAC to be examined? | 9<br>6 | 3<br>3 | 3<br>3 |
| 4 | a) List out and explain the analytical method validation parameters.<br>b) Write short notes on Computerized System Validation. | 10<br>5 | 4<br>4 | 2<br>2 |
| 5 | a) What is a Patent? Explain the procedure for filing an application for a patent in India.<br>b) Write the role of Intellectual property in the pharmaceutical industry. | 9<br>6 | 5<br>5 | 2<br>2 |
| 6 | a) Explain the criteria of patentability of an invention and steps in patent application.<br>b) Write a short note on the Digital significance of 21 CFR part II. | 7<br>8 | 5<br>4 | 3<br>3 |
| 7 | a) Evaluate the different phases of water system validation?<br>b) Explain the procedure involved in qualification and calibration of HPLC. | 10<br>5 | 3<br>2 | 5<br>3 |
| 8 | a) Explain about User requirement specification<br>b) Illustrate the process of re-validation process. | 8<br>7 | 1<br>1 | 3<br>4 |

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**M.Pharmacy (Common Paper for all) I Semester (PCI) (Supple) Examination Jul/Aug 2024**

**Subject & Code:** Modern Pharmaceutical Analytical Techniques & MPH101T

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

**PART- A**

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

| Q.No. | Question | Marks | CO | BL |
|---|---|---|---|---|
| 1 | a) State Beers-Lambert's Law | 5 | 1 | 1 |
| | b) Write the instrumentation of FT-IR | 10 | 1 | 3 |
| 2 | a) What is chemical shift and write the factors effecting chemical shift | 10 | 2 | 3 |
| | b) Explain spin-spin coupling and give the applications of NMR | 5 | 2 | 2 |
| 3 | a) Write in detail different ions formed in Mass Spectrometry and their significance | 5 | 3 | 3 |
| | b) Explain in detail different ionization techniques of Mass Spectrometry | 10 | 3 | 2 |
| 4 | a) Write the working principle and different detectors used in Gas Chromatography | 8 | 4 | 3 |
| | b) Elaborate the principle and instrumentation of HPLC | 7 | 4 | 5 |
| 5 | a) Define and discuss various X-ray powder techniques | 7 | 5 | 1 |
| | b) Write the instrumentation and applications of Gel Electrophoresis | 8 | 5 | 2 |
| 6 | a) Indicate the Principle and applications of potentiometer | 5 | 6 | 2 |
| | b) Write the principle, instrumentation and applications of DSC | 10 | 6 | 3 |
| 7 | a) Define Atomic Absorption Spectroscopy and write the principle and instrumentation. | 7 | 1 | 1 |
| | b) Write a note on Quenching and give applications of fluorescence spectrophotometer. | 8 | 1 | 3 |
| 8 | a) Write the principles, different methods and modes of capillary electrophoresis | 5 | 5 | 3 |
| | b) Elaborate the Instrumentation of High Performance Thin Layer Chromatography (HPTLC) | 10 | 4 | 3 |

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**M.Pharmacy (Common to all) I Semester (PCI) (Main) Examination Feb/March 2024**

**Subject:** Modern Pharmaceutical Analytical Techniques – MPL101T

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

**PART- A**

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

| Q.No. | Question | Marks | CO | BL |
|---|---|---|---|---|
| 1 | a) State short note on Beers-Lambert's Law | 3 | 1 | 1 |
| | b) Write the factors effecting vibrational frequencies and instrumentation of FT-IR | 12 | 1 | 3 |
| 2 | a) What is chemical shift and write the factors effecting chemical shift | 10 | 2 | 5 |
| | b) Explain coupling constant and its significance in NMR | 5 | 2 | 2 |
| 3 | a) Write in detail different ions formed in Mass Spectrometry and their significance | 5 | 3 | 3 |
| | b) Explain in detail different ionization techniques of Mass Spectrometry | 10 | 3 | 2 |
| 4 | a) Write the principle and working of detectors used in HPLC | 7 | 4 | 3 |
| | b) Elaborate the principle and instrumentation of Gas Chromatography | 8 | 4 | 5 |
| 5 | a) Define and discuss various X-ray powder techniques | 10 | 5 | 1 |
| | b) Write the instrumentation and applications of Ion exchange chromatography | 5 | 5 | 2 |
| 6 | a) Indicate the Principle and applications of potentiometer | 5 | 6 | 2 |
| | Write the principle, instrumentation and applications of DTA | 10 | 6 | 3 |
| 7 | a) Write the Principle and instrumentation Atomic Absorption Spectroscopy. | 8 | 1 | 3 |
| | b) Write a note on Quenching and give appellations of fluorescence spectrophotometer. | 7 | 1 | 3 |
| 8 | a) Write the principles, different methods and modes of capillary electrophoresis | 5 | 5 | 3 |
| | b) Elaborate the Instrumentation of High Performance Thin Layer Chromatography (HPTLC) | 10 | 4 | 3 |

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**M.Pharmacy (Ph.Analysis) I Semester (PCI) (Main) Examination Feb/March 2024**

**Subject: Pharmaceutical Validation-MPA103T**

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

**PART- A**

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

| Q.No. | Question | Marks | CO | BL |
|---|---|---|---|---|
| 1 | a) Define qualification and explain the different phases of qualification process of analytical Equipment's. | 8 | 1 | 1 |
| | b) Define validation and explain the types of process validation. | 7 | 1 | 1 |
| 2 | a) Explain the procedure involved in qualification and calibration of HPTLC. | 8 | 2 | 3 |
| | b) Explain the calibration procedure of glassware used in analytical work. | 7 | 2 | 3 |
| 3 | a) Explain about Sampling methods for cleaning validation. | 8 | 3 | 2 |
| | b) Write short notes on Compressed air and nitrogen. | 7 | 3 | 3 |
| 4 | a) Describe the Method Validation parameters for new Analytical method. | 10 | 4 | 2 |
| | b) Write short notes on GAMP 5. | 5 | 4 | 2 |
| 5 | a) What is an intellectual property right? Explain about different types of IPR. | 8 | 5 | 5 |
| | b) Elaborate the role of Intellectual property in pharmaceutical industry. | 7 | 5 | 5 |
| 6 | a) Write about PCT and WIPO. | 8 | 5 | 2 |
| | b) Write short notes on electronic records. | 7 | 4 | 2 |
| 7 | a) Discuss about pharmaceutical water system validation. | 10 | 3 | 3 |
| | b) Explain the procedure involved in qualification and calibration of FTIR. | 5 | 2 | 3 |
| 8 | a) Outline factory acceptance test and site acceptance test? | 8 | 1 | 4 |
| | b) Explain the steps involved in preparation of validation master plan (VMP). | 7 | 1 | 4 |

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**M.Pharmacy (Pharmaceutical Analysis) I Semester (PCI) (Main) Examination Feb/March 2024**

**Subject: FOOD ANALYSIS-MPA104T**

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

**PART- A**

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

| Q.No. | Question | Marks | CO | BL |
|---|---|---|---|---|
| 1 | a) Outline the general methods used to analyze proteins and amino acids in food.<br>b) Discuss in detail various colorimetric methods of analysing proteins and aminoacids. | 5<br>10 | 2<br>2 | 1<br>2 |
| 2 | a) Recall the general methods used for the analysis of food spoilage due to lipid oxidation.<br>b) Describe any three tests used to evaluate oxidative stability of lipids in foods. | 7<br>8 | 1<br>2 | 1<br>2 |
| 3 | a) Describe the methods of detection for natural pigments.<br>b) Differentiate between permitted and non-permitted synthetic dyes and their usage. | 8<br>7 | 3<br>3 | 2<br>2 |
| 4 | a) Propose a method for detecting the presence of water as an adulterant in milk.<br>b) Compare and contrast the analytical techniques used for testing the quality of liquid milk and powdered milk. | 5<br>10 | 3<br>3 | 3<br>2 |
| 5 | a) Given a scenario, recommend a suitable analytical technique for detecting organochlorine pesticides.<br>b) Evaluate the environmental impact of organophosphorus pesticides compared to organochlorine pesticides. | 7<br>8 | 5<br>5 | 3<br>4 |
| 6 | a) Evaluate the role of FDA in responding to food safety incidents.<br>b) Design a quality control checklist based on BIS standards for a food manufacturing unit. | 6<br>9 | 6<br>6 | 5<br>6 |
| 7 | a) Recall the specific methods used to analyze Mono- and Oligosaccharides in food.<br>b) Explain the concepts of protein separation with special emphasis on PAGE. | 7<br>8 | 4<br>2 | 1<br>2 |
| 8 | a) Name the principles involved in the chemical assay of B-series vitamins.<br>b) Comprehend the role of chromatographic techniques in the analysis of pesticides. | 7<br>8 | 2<br>4,5 | 1<br>2 |

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**M.Pharmacy (Ph.Analysis) I Semester (PCI) (Main) Examination Feb/March 2024**

**Subject:** Advanced Pharmaceutical Analysis MPA102T

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

**PART- A**

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

| Q. No. | Question | Marks | CO | BL |
|---|---|---|---|---|
| 1 | a) Define Impurity and write the classification of impurities in API and drug substances.<br>b) Explain the different methods for quantification of impurities in API and drug products. | 5<br>10 | 1<br>1 | 1<br>2 |
| 2 | a) Write a short note on the qualification of degradation products.<br>b) How is photostability of formulations performed? | 5<br>10 | 3<br>3 | 1<br>2 |
| 3 | a) What is impurity profiling and explain its importance in the testing of pharmaceutical products?<br>b) Write about ICH stability guidelines for biological products. | 7<br>8 | 1<br>3 | 2<br>1 |
| 4 | a) Write the potential sources of elemental impurities.<br>b) Give the classification of residual solvents and their limits in drug substances and drug products. | 5<br>10 | 2<br>1 | 1<br>4 |
| 5 | a) Describe the principle and procedure involved in the biological assay of Heparin sodium.<br>b) What is an antitoxin. Explain the biological assay of Tetanus antitoxin. | 7<br>8 | 5<br>5 | 2<br>2 |
| 6 | a) Explain in detail Enzyme Immuno assay. Give examples?<br>b) Describe about Radio immuno assay with examples? | 8<br>7 | 6<br>6 | 2<br>2 |
| 7 | Propose the steps involved in the method development and validation of impurity profiling of any drug? | 15 | 1 | 6 |
| 8 | a) What are accelerated stability studies and how is the shelf life of drug products calculated?<br>b) Write about HPTLC as finger printing tool in stability testing of phytopharmaceuticals. | 7<br>8 | 3<br>4 | 5<br>4 |

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