Code. No.M032511CP

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M.Pharmacy (Common for all) I Sem (PCI) (Main & Backlog) Examination Mar/ Apr 2025

Subject: Modern Pharmaceutical Analytical Techniques

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 and derive Beer lamberts law. Add a note on its limitations.	8	1	1
	b) Explain different regions in IR spectroscopy and also discuss about detectors used.	7	1	2
2	a) What are Quenchers? Discuss the different types of Quenching	5	1	2
	b) What is Chemical shift? Explain with examples different factors influencing chemical shift.	10	2	2
3	a) Categorize different peaks observed in MS and explain isotope peaks with examples.	7	3	4
	b) Enlist the different Ionizers used in MS and explain any three in detail.	8	3	2
4	a) Explain the pumps and detectors used in HPLC.	8	4	2
	b) Discuss HPTLC and its applications.	7	4	2
5	a) Write the Principle and working conditions of paper Electrophoresis	8	5	3
	b) Classify the types of crystals and add a note on applications of X ray diffraction	7	5	3
6	a) Enlist the different electrodes used in Potentiometry and explain the construction and working of any one electrode.	8	6	1
	b) Write the Principle of TGA, What factors are responsible for affecting TGA results and write the applications of TGA.	7	6	3
7	a) Explain the sampling techniques in IR spectroscopy	7	1	2
	b) Create MS Spectrum for any two compounds and explain its peaks.	8	3	6
8	a) Add a note on Shielding and deshielding	8	2	1
	b) Enlist and explain the detectors used in Gas chromatography	7	4	1

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M.Pharmacy (Pharmaceutical Analysis) I Semester (PCI) (Main & Backlog) Examination
Mar/ Apr 2025

Subject: Advance 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) Mention the process of listing & Qualification of degradation products with specifications as per ICH in new drug products?	7	1	1
	b) Describe the Limits, reporting levels and analytical procedures for the residual solvents?	8	1	2
2	a) Classify Elemental impurities and their potential sources?	6	2	2
	b) Discuss the procedure of stability testing protocol with respect to storage conditions, specification and test parameters as per ICH?	9	2	2
3	a) Explain the method development steps involved in impurity profiling?	7	3	2
	b) Describe the stability guidelines for biological products as per ICH?	8	4	2
4	a) Define the term fingerprinting and its importance in standardization by HPTLC with examples?	9	5	1
	b) Explain the drug interactions and complexity with herbals?	6	4	2
5	a) Write about the Bioassay methods for the Antivenom, Rabies and Oxytocin Vaccines?	8	6	3
	b) Explain the Principle and Instrumentation of PCR?	7	6	2
6	a) Discuss the techniques Enzyme IA and Fluoro IA with Applications?	8	6	2
	b)) Describe different methods for the separation of bound and unbound drug?	7	6	2
7	a) Write about the factors like Temperature and Dielectric constant affecting stability studies?	7	2	3
	b) Explain in detail the Instrumentation of C,H,N & S analyzer?	8	2	2
8	a) Classify Residual solvents and report their Limits?	5	1	2
	b) Mention the Analytical tools used in the degradation characterization and also Photostability testing guidelines?	10	2	1

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M.Pharmacy (Pharmaceutical Analysis) I Semester (PCI) (Main & Backlog) Examination
Mar/ Apr 2025

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. b) Explain about validation master validation.	8M 7M	1 1	1 2
2	a) Explain the calibration procedure of glassware used in analytical work. b) Different steps involved in the calibration of HPLC instrument.	7M 8M	2 2	2 1
3	a) Explain about cleaning validation process in detail. b) write a note on the importance of HVAC system in the pharmaceutical industry?	8M 7M	3 3	2 4
4	a) Define Validation. Describe method validation parameters as per ICH & USP guidelines. b) Write a short note on the electronic records and Digital significance of 21 CFR part 11.	8M 7M	4 4	1 1
5	a) What is a Patent? Explain the procedure for filing an application for a patent in India. b) Write the role of Intellectual property in the pharmaceutical industry.	8M 7M	5 5	1 2
6	a) Explain the criteria of the patentability of an invention and the steps in the patent application. b) Describe about Validation Process.	8M 7M	5 1	2 2
7	a) what SAT and FAT? b) Explain about User requirement specification.	9M 5M	1 1	1 2
8	a) Describe qualification procedure of FTIR instrument. b) Brief about Pharmaceutical water system validation.	8M 7M	2 3	1 2

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M.Pharmacy (Pharmaceutical Analysis) I Semester (PCI) (Main & Backlog) Examination
Mar/ Apr 2025

Subject: FOOD ANALYSIS & MPA 104T

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 Carbohydrates and give the general methods for the analysis of Carbohydrates b) Applications of Food Carbohydrates	10 M 05 M	2 2	2 1
2	a) Enumerate the Physiochemical properties of proteins b) Explain the principle and Procedure in Kjeldahl and colorimetric methods for the quantitative estimation of Proteins	05 M 10 M	2 2	2 2
3	a) What is adulteration? Explain the methods to determine the adulteration of fats and oils b) Write a detailed note on lipids and its classification with examples	10 M 05 M	4 4	2 1
4	a) Differentiate between fat soluble and water soluble vitamins b) List out the specific test organisms employed in microbial assay of Vitamins and its methodology.	05 M 10 M	3 3	2 1
5	Discuss in detail about method of detection of permitted and non permitted dyes	15 M	4	2
6	Explain the principle and procedure involved in the analysis of Anti oxidants used in the food industry	15 M	3	2
7	a) Define fermentation Products. Explain its types. b) Enumerate and explain the method of analysis of wine, beer and spirits.	05 M 10 M	4 4	1 2
8	a) Summarize in detail the methods on the analysis of Pesticides b) Write about the AGMARK	10 M 05 M	5 6	2 1

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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. b) Write about validation master validation.	8 7	1 1	1 1
2	a) Explain the procedure involved in qualification and calibration of GC. b) Explain the steps involved in the calibration of analytical balance.	8 7	2 2	3 3
3	a) Explain about cleaning validation process in detail. b) Elaborate on parameters in HVAC to be examined?	9 6	3 3	3 3
4	a) List out and explain the analytical method validation parameters. b) Write short notes on Computerized System Validation.	10 5	4 4	2 2
5	a) What is a Patent? Explain the procedure for filing an application for a patent in India. b) Write the role of Intellectual property in the pharmaceutical industry.	9 6	5 5	2 2
6	a) Explain the criteria of patentability of an invention and steps in patent application. b) Write a short note on the Digital significance of 21 CFR part II.	7 8	5 4	3 3
7	a) Evaluate the different phases of water system validation? b) Explain the procedure involved in qualification and calibration of HPLC.	10 5	3 2	5 3
8	a) Explain about User requirement specification b) Illustrate the process of re-validation process.	8 7	1 1	3 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. b) Discuss in detail various colorimetric methods of analysing proteins and aminoacids.	5 10	2 2	1 2
2	a) Recall the general methods used for the analysis of food spoilage due to lipid oxidation. b) Describe any three tests used to evaluate oxidative stability of lipids in foods.	7 8	1 2	1 2
3	a) Describe the methods of detection for natural pigments. b) Differentiate between permitted and non-permitted synthetic dyes and their usage.	8 7	3 3	2 2
4	a) Propose a method for detecting the presence of water as an adulterant in milk. b) Compare and contrast the analytical techniques used for testing the quality of liquid milk and powdered milk.	5 10	3 3	3 2
5	a) Given a scenario, recommend a suitable analytical technique for detecting organochlorine pesticides. b) Evaluate the environmental impact of organophosphorus pesticides compared to organochlorine pesticides.	7 8	5 5	3 4
6	a) Evaluate the role of FDA in responding to food safety incidents. b) Design a quality control checklist based on BIS standards for a food manufacturing unit.	6 9	6 6	5 6
7	a) Recall the specific methods used to analyze Mono- and Oligosaccharides in food. b) Explain the concepts of protein separation with special emphasis on PAGE.	7 8	4 2	1 2
8	a) Name the principles involved in the chemical assay of B-series vitamins. b) Comprehend the role of chromatographic techniques in the analysis of pesticides.	7 8	2 4,5	1 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. b) Explain the different methods for quantification of impurities in API and drug products.	5 10	1 1	1 2
2	a) Write a short note on the qualification of degradation products. b) How is photostability of formulations performed?	5 10	3 3	1 2
3	a) What is impurity profiling and explain its importance in the testing of pharmaceutical products? b) Write about ICH stability guidelines for biological products.	7 8	1 3	2 1
4	a) Write the potential sources of elemental impurities. b) Give the classification of residual solvents and their limits in drug substances and drug products.	5 10	2 1	1 4
5	a) Describe the principle and procedure involved in the biological assay of Heparin sodium. b) What is an antitoxin. Explain the biological assay of Tetanus antitoxin.	7 8	5 5	2 2
6	a) Explain in detail Enzyme Immuno assay. Give examples? b) Describe about Radio immuno assay with examples?	8 7	6 6	2 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? b) Write about HPTLC as finger printing tool in stability testing of phytopharmaceuticals.	7 8	3 4	5 4

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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.	5	2	1
	b) Discuss in detail various colorimetric methods of analysing proteins and aminoacids.	10	2	2
2	a) Recall the general methods used for the analysis of food spoilage due to lipid oxidation.	7	1	1
	b) Describe any three tests used to evaluate oxidative stability of lipids in foods.	8	2	2
3	a) Describe the methods of detection for natural pigments.	8	3	2
	b) Differentiate between permitted and non-permitted synthetic dyes and their usage.	7	3	2
4	a) Propose a method for detecting the presence of water as an adulterant in milk.	5	3	3
	b) Compare and contrast the analytical techniques used for testing the quality of liquid milk and powdered milk.	10	3	2
5	a) Given a scenario, recommend a suitable analytical technique for detecting organochlorine pesticides.	7	5	3
	b) Evaluate the environmental impact of organophosphorus pesticides compared to organochlorine pesticides.	8	5	4
6	a) Evaluate the role of FDA in responding to food safety incidents.	6	6	5
	b) Design a quality control checklist based on BIS standards for a food manufacturing unit.	9	6	6
7	a) Recall the specific methods used to analyze Mono- and Oligosaccharides in food.	7	4	1
	b) Explain the concepts of protein separation with special emphasis on PAGE.	8	2	2
8	a) Name the principles involved in the chemical assay of B-series vitamins.	7	2	1
	b) Comprehend the role of chromatographic techniques in the analysis of pesticides.	8	4,5	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.	5	1	1
	b) Explain the different methods for quantification of impurities in API and drug products.	10	1	2
2	a) Write a short note on the qualification of degradation products.	5	3	1
	b) How is photostability of formulations performed?	10	3	2
3	a) What is impurity profiling and explain its importance in the testing of pharmaceutical products?	7	1	2
	b) Write about ICH stability guidelines for biological products.	8	3	1
4	a) Write the potential sources of elemental impurities.	5	2	1
	b) Give the classification of residual solvents and their limits in drug substances and drug products.	10	1	4
5	a) Describe the principle and procedure involved in the biological assay of Heparin sodium.	7	5	2
	b) What is an antitoxin. Explain the biological assay of Tetanus antitoxin.	8	5	2
6	a) Explain in detail Enzyme Immuno assay. Give examples?	8	6	2
	b) Describe about Radio immuno assay with examples?	7	6	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?	7	3	5
	b) Write about HPTLC as finger printing tool in stability testing of phytopharmaceuticals.	8	4	4

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