Code. No. **M5022414**

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St. Pauls College of Pharmacy UGC AUTONOMOUS R.R. Dist.

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: 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 (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: 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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