

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	СО	BL
	a) Write about factory acceptance test and site acceptance test.	8	1	1
1	b) Write about validation master validation.	7	1	1
2	a) Explain the procedure involved in qualification and calibration of GC.	8	2	3
2	b) Explain the steps involved in the calibration of analytical balance.	7	2	3
3	a) Explain about cleaning validation process in detail.	9	3.	3
3	b) Elaborate on parameters in HVAC to be examined?	6	3	3
4	a) List out and explain the analytical method validation parameters.	10	4	2
4	b) Write short notes on Computerized System Validation.	5	4	
	by write short hotel on company			2
5	a) What is a Patent? Explain the procedure for filing an application for a	9	5	2
5	patent in India. b) Write the role of Intellectual property in the pharmaceutical industry.	6	5	2
6	a) Explain the criteria of patentability of an invention and steps in patent application.	7	5	3
(Logge	b) Write a short note on the Digital significance of 21 CFR part II.	8	4	3
7	a) Evaluate the different phases of water system validation?	10	3	5
	b) Explain the procedure involved in qualification and calibration of HPLC.	5	2	3
8	a) Explain about User requirement specification	8	1	3
_	b) Illustrate the process of re-validation process.	7	1	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	What is chemical shift and write the factors effecting chemical shift	10	2	3
	 Explain spin-spin coupling and give the applications of NMR 	5	2	2
3	Write in detail different ions formed in Mass Spectrometry and their significance	5	3	3
	 Explain in detail different ionization techniques of Mass Spectrometry 	10	3	2
4	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
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	 Define Atomic Absorption Spectroscopy and write the principle and instrumentation. 	7	1	1
	 Write a note on Quenching and give applications of fluorescence spectrophotometer. 	8	1	3
8	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

Subject: Modern Pharmaceutical Analytical Techniques MPL101T

Time: 3 Hours

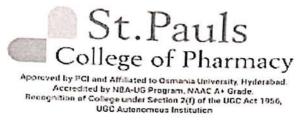
Max.Marks: 75

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 Lawin (1991)		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	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
ı	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	Write the principles, different methods and modes of capillary electrophoresis	5	5	3
	 Elaborate the Instrumentation of High Performance Thin Layer Chromatography (HPTLC) 	10	4	3







M.Pharmacy (Ph.Analysis) I Semester (PCI) (Main) Examination Feb/Mar

Subject: Pharmaceutical Validation-MPA103T

Time: 3 Hours

Aniiks:175

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.	Hilli811,	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	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 Méthod 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	8	5	5
	IPR. The role of Intellectual property in pharmaceutical industry.	7	5	5
6/1/1	a) Write about PCT and WIPO.	8	5	2
([[]]]	b) Write short notes on electronic records.	7	4	2
	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	1





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M.Pharmacy (Pharmaceutical Analysis) 1 Semester (PCI) (Main) Examination Feb/March 2024

Subject: FOOD ANALYSIS-MPA104T

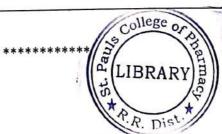
Time: 3 Hours

Max.Marks: 75

PART- A

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

Q.No.		Marks	CO	BL
1	a) Outline the general methods used to analyze proteins and amino acids][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 matural 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	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
0	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 MPA 102T

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
(11)	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
,111	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

