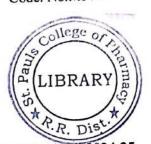




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## M.Pharmacy (Pharmaceutical Analysis) II Semester (PCI) (Supply) Examination Dec/ Jan 2024-25

Subject: Advanced Instrumental Techniques (MPA201T)

Time: 3 Hours

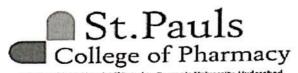
Max.Marks: 75

#### PART- A

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

Q.No.	Question	Marks	CO	BL
1	a) Outline the principles and applications of ultra,nano liquid chromatography in pharmaceutical analysis.	8	1	1
	b) Discuss the practical aspects of preparative HPLC.	7	.1	2
2	a) Illustrate the principle and instrumentation involved in Gas chromatography.	10	2	4
	b) Compute LC-NMR hyphenated techniques.	5	2	3
3	a) Describe the principle and instrumentation in supercritical fluid chromatography	8	3	2
	b) Enumerate the advantages of using crown ethers as buffer additives in capillary electrophoresis.	7	3	3
4	a) Compose the different applications of mass spectrometry	5	4	5
	b) Conclude LC-MS hyphenation and mass analyzers.	10	4	4
5	a) Design. instrumentation of NMR.	8	5	6
	b) Explain the important applications of C13 NMR	7	5	4
6	a) Describe the principle and instrumentation involved in affinity chromatography.	10	2	2
	b) Elaborate the different columns in gas chromatography.	5	2	4
7	a) Contrast the principles of FT-NMR with C13 NMR	7	5	4
	b) Demonstrate the Advances in enantiomeric separation.	8	1	2
3	<ul> <li>a) Recall the Methods and modes of Capillary Electrophoresis.</li> </ul>	7	3	1
	b) Categorize Metastable ion, Isotopic peaks, Base peak, MALDI	8	4	4





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## M.Pharmacy (Pharmaceutical Analysis) II Sem (PCI) (Supply) Examination Dec / Jan 2024-25

Subject: Quality Control & Quality Assurance & MPA203T

Time: 3 Hours

Max.Marks: 75

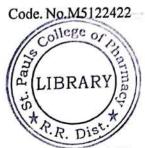
#### PART- A

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

Qu	e NO	Questions	Marks	CO	BL
Q.1	(a)	Illustrate ICH Q3 guidelines	7.5	3	4
	(b)	Write good practices followed sampling of raw materials	7.5	1	2
Q.2	(a)	What are the requirements of an organization and personnel as per USFDA?	7.5	2	2
	(b)	Write a brief note on ICH Q6 guidelines	7.5	3	2
Q.3	(a)	Briefly discuss CPCSEA guidelines	7.5	2	2
	(b)	Justify GLP is essential part of Pharmaceutical Industry by describing about GLP in detail.	7.5	1	5
Q.4	(a)	Discuss Purchase specifications and maintenance of stores for raw materials.	7.5	1	2
	(b)	Illustrate concept, components of Quality control and Quality assurance.	7.5	1	4
Q.5	(a)	Write a note on SOP	7.5	4	1
	(b)	Identify how documents to be maintained by the quality control department.	7.5	4	3
Q. 6	(a)	Explain the maintenance of sterile areas.	7.5	5	1
	(b)	Briefly discuss Batch formula Record & Master formula Record	7.5	5	1
Q. 7	(a)	Write note on control of contamination as per GMP Guideline	7.5	5	2
	(b)	Write a note on cGMP guidelines according to schedule M.	7.5	1	2
Q. 8	(a)	Construct detailed role/importance of IPQC tests in quality in any finished pharmaceutical products? Explain various IPQC test for solid and parenteral products	15	3	6



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### M.Pharmacy (Pharmaceutical Analysis) II Semester (PCI) (Supply) Examination Dec/ Jan 2024-25

Subject & Code: Modern Bio Analytical Techniques & MPA202T

Time: 3 Hours

William .

Max.Marks: 75

#### PART-A

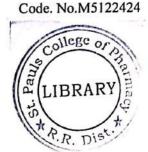
Note: Answer any FIVE questions. All questions carry equal marks.

Q.No.	Question	Marks	CO	BL
1	a) Write about basic consideration of Pharmacokinetics and explain about	10M	3	2
1	Pharmacokinetic and Pharmacodynamic drug interactions.			
	b) Illustrate the LC-MS in bioactivity screening.	5M	3	3
2	Write about dissolution and drug releasing testing.	7M	2	1
	b) Explain in detail about Biopharmaceutical factors affecting drug			
	Bioavailability.	8M	2	2
3	a) Explain the principle, procedure involved in extraction of drugs and	8M	1	3
	metabolites from biological matrices by liquid liquid extraction.			
	b) Explain the EMEA guidelines for bio analytical method validation.	7M	1	2
4	a) Explain about bioavailability, purpose of bio availability studies,	10M	5	2
	relative and absolute bioavailability and methods for assessing			
	bioavailability. b) Explain about microsomal assays.	5M	5	2
	b) Explain about interosonial assays.	SIVI	3	2
5	a) Describe drug interactions linked to transporters.	8M	3	2
1	b) Explain about cytochrome P450 based drug interactions.	7M	3	2
6	Write about general procedure for cell culture, isolation of cells,	10M	4	
	subculture and characterisation of cells and their applications.	TOM	4	2
	c) Write about the principle and applications of MTT assay.	534		
7		5M	4	3
7	a) Explain the methods of assessing bioavailability study.	7M	5	5
	b) Enumerate the sample preparation to study Metabolites by using Rat	8M	5	4
	Liver Microsome.			
8	Write a note on			
	<ul> <li>General principle and procedure involved in Protein Precipitation</li> </ul>	8M	1	2
	b) PK-PD drug interactions.	7M	3	4





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## M.Pharmacy (Pharmaceutical Analysis) II Semester (PCI) (Supply) Examination Dec/ Jan 2024-25

Subject: Herbal And Cosmetic Analysis & MPA204T

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) Write a brief note on WHO guidelines for herbal drug standardization.	7 +8	1	1
	b) write the comparative study between herbal vs conventional drugs.			2
2	a) Illustrate with examples bio drug-drug interactions.	7+8	4	2
	b) What are the different types of adulteration / substitutions of herbal drugs? Give examples for each.			2
3	a) How will you determine acid value and iodine value for an herbal cosmetic? Write its significance.	8+7	5	3
	b) What are causes and measures of herbal drug adulterations?		2	1
4	a) How will you determine the following toxicity in herbal formulations?     i) Heavy metals ii) Pesticide residues	8+7	2	4
	b) Write the protocol for stability testing of natural products.		3	5
5	a) Elaborate the WHO guidelines in quality assessment of herbal drugs.	8+7	3	2
	b) What are the challenges in monitoring the safety of herbal medicines? Give examples.		4	3
6	Write the general methods of analysis of hair products and skin creams by BIS standards.	15	5	2
7	a) Write an assay on adulterant screening of natural products and drugs using modern analytical instruments.	7+8	2	2
	b) How will you determine the following? i) Ash value ii) Moisture content iii) Fineness of powder.		5	2
8	<ul> <li>a) Give the applications of spontaneous reporting scheme for bio drug adverse reactions.</li> </ul>	8+7	4	3
	b) Explain Bio drug-food interactions with few examples.			2



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## M.Pharmacy (Pharmaceutical Analysis) II Semester (PCI) (Main) Examination Jul/Aug 2024

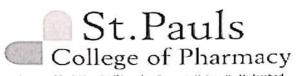
Subject & Code: MPA203T- Quality Control & Quality Assurance & MPA203T

Time: 3 Hours Max.Marks: 75

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

One	. No	Question	Marks	CO	BL
1	(a)	Illustrate cGMP guidelines according to schedule M.	7.5	1	3
3005	(b)	Explain the difference between Quality Control and Quality Assurance activities	7.5	1	2
2	(a)	Write a note on IPQC test for Tablets	7.5	3	1
	(b)	Justify 'quality audit' is important for quality control in Pharmaceutical industry by describing details about Quality Audit	7.5	5	5
3	(a)	Explain the guidelines for sanitation of manufacturing premises.	7.5	5	2
	(b)	Discuss Good Warehousing Practice in Pharmaceutical industry	7.5	5	2
4	(a)	Describe the quality control test for containers, closures and secondary packing materials	7.5	5	3
	(b)	Write a brief note on ICH Q6 guidelines	7.5	3	1
5	(a)	Illustrate the Good laboratory practices for a quality control laboratory in detail.	7.5	1	3
	(b)	Describe about CPCSEA guidelines in detail.	7.5	2	2
	(a)	Define IPQC. Write note on IPQC test for cream.	7.5	3	1
	(b)	Illustrate process of control of contamination as per GMP Guideline	7.5	4	3
7	(a)	Write a note on Distribution records	7.5	4	1
	(b)	Illustrate detail about Standard operating procedures	7.5	5	3
8	(a)	Construct a detailed discussion on following:  (i)Drug product inspection, (ii)Expiry date calculation, (iii)Calculation of yields,  (iv) Production record review	15	4	6

Code. No. M5082424



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## M.Pharmacy (Pharmaceutical Analysis) 11 Semester (PCI) (Main) Examination Jul/Aug 2024

Subject & Code: Herbal and Cosmetic Analysis & MPA 204T

Time: 3 Hours Max.Marks: 75

#### PART- A

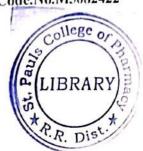
Note: Answer any FIVE questions. All questions carry equal marks.

Q.No.	Question	Marks	CO	BL
1	Enumerate and explain the different methods of DNA finger printing in the identification of natural drugs with suitable diagrams.	15	2	5
2	Write in detail about spontaneous reporting schemes for bio-drug adverse reactions, drug-drug and drug-food interactions with suitable examples.	15	4	2
3	Elaborate the Indian standard specifications laid down for sampling and testing various cosmetics in baby care products.	15	5	3
4	<ul><li>a) Discuss the standard protocol for stability testing of natural products.</li><li>b) Write in detail about monograph of herbal drugs as per IP.</li></ul>	10 5	3	4
5	Write about the different challenges faced in monitoring the safety of herbal medicine.	15	4	2
6	Write in detail about herbal drug standardization guidelines as per WHO & Ayush guidelines.	15	1	3
7	Write a detailed note on Quality of raw materials used in cosmetic manufacture as per BIS.	15	5	1
8	Discuss about Indian and International patent laws applicable to herbal drugs and natural products.	15	2	2

Code.No.M5082422



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# M.Pharmacy(PharmaceuticalAnalysis)IISemester(PCI)(Main)ExaminationJul/Aug2024

Subject&Code: Modern Bio Analytical Techniques&MPA202T

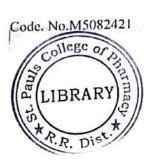
Time: 3Hours

 ${\bf Note: Answer any FIVE questions. All questions carry equal marks.}$ 

Max.Marks:75

ON	Overtion	Marks	CO	DL
Q.No.	Question	8M W	3	2
I	a) Writeaboutthetoxicokineticevaluationinpreclinicalstudies.			
	i i i O - vicelvinatios tudios	7M	3	2
	b) Explainimportanceandapplicationsoftoxicokineticstudies.	8M	2	1
2	a) Writeindetailaboutalternativemethodsofdissolutiontestingtransport	OIVI	4	
_	Models.			
		22232		١.
	b) Writetheexperimentalmethodsforsolubility.	7M	2	1
3	a)ExplainaboutthedifferentBio-analyticalmethodsforextractionof	8M	1	3
3	a)Explanabouthed interest and in a second			
	Drugsfrombiologicalmatrices.			
	b) DescribetheUSFDAguidelinesforbio-analyticalmethodvalidation.	7M	1	2
	b) Describellie OSP DAguide intestorio danary dedininativa	10M	5	2
4	a)Explainindetailaboutstudydesignandcrossoverstudydesignin drug	10111		-
	Productperformance.			
		5M	5	3
	b) Explainaboutgenericbiologics.	Villaging.		
5	a)ExplainindetailaboutBiopharmaceuticalfactorsaffectingdrug	8M	2	2
	Bioavailability.			
	b)ExplainIn-situandIn-vivopermeabilitytestingmethods.	7M	2	2
6	a) Writeaboutprincipleandapplications of:	10M	4	2
0				
1	1)Cellviabilityassays (5M)			
11	2)Flowcytometry.(5M)	5M	4	1
	b) Writeanoteon Cryopreservation.		-	
7	a) Whataretheregulatoryaspectsfollowedformetaboliteidentification?	7M	5	2
		200.00	533	772
	b) EnumeratethesamplepreparationtostudymetabolitesbyHuman	8M	5	4
	Liver Microsomes.			
8	Writeanoteon			
8		8M	5	l 1
	a) ClinicalsignificanceofBioequivalencestudies.	J.,.	Ĭ	<sup>*</sup>
		7M	5	1
	b) Biosimilar products.	/1/1	را	1





## M.Pharmacy (Pharmaceutical Analysis) II Semester (PCI) (Main) Examination Jul/Aug 2024

Subject & Code: Advanced Instrumental Analysis & MPA201T

Time: 3 Hours

Max.Marks: 75

#### PART- A

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

		100	117500000	
Q.No.	Question	Marks	CO	BL
1.	A. Revise the importance of HPLC in chiral analysis of	17	1	2
	Pharmaceuticals.	8	1	2
	B. Give the details of Construction and instrumentation of HRLC.	1823		
2	A. Categorize the different derivatization techniques in Gas	8	2	4
	chromatography.	1		
	B. Evaluate the stationary and mobile phases in ion exchange	7	2	5
	chromatography.	1		
3	A. Describe the instrumentation of super critical fluid	8	3	2
	chromatography	7	3	1
	B. Outline the applications of CE-MS hyphenation techniques.	1 2 2 2		_
1	<ol> <li>A. Illustrate the mass fragmentation pattern by giving an example.</li> </ol>	8	4	3
- 1	B. Explain the instrumentation involved in mass spectroscopy.	7	4	2
-	A Outline the different factors influencing chemical shift	7	5	1
5	B. Differentiate between C13 NMR and H1 NMR	1 850	7.75	
	B. Differentiate between Capitalia in 1441	8	5	2
5	A. Explain the principle and instrumentation involved size exclusion	8	2	2
	chromatography.	7	3	3
Y	B. Execute the developmental techniques of capillary electrophoresis			3
7	A. Design and instrumentation in HPTLC and their advantages	8	2	6
	B. Elaborate the different ionization techniques in mass spectrometry	7	4	4
3	A. Justify the Immobilized Polysaccharide CSPs	8	1	5
	B. Describe the NOSY and COSY techniques.	7	5	1