Code. No. M5082423

St. Pauls College of Pharmacy

Approved by PCI and Affiliated to Osmania University, Hyderabad.
Accredited by NBA-UG Program, NAAC A+ Grade.
Recognition of College under Section 2(f) of the UGC Act 1956,
UGC Autonomous Institution

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.

Que. No		Question	Marks	CO	BL
1	(a)	Illustrate cGMP guidelines according to schedule M.	7.5	1	3
	(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
6	(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

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M.Pharmacy (Pharmaceutical Analysis) II 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	a) Discuss the standard protocol for stability testing of natural products. b) Write in detail about monograph of herbal drugs as per IP.	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

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

Subject&Code: Modern Bio Analytical Techniques&MPA202T

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

Note: AnsweranyFIVEquestions.Allquestionscarryequalmarks.

Q.No.	Question	Marks	CO	BL
1	a) Writeaboutthetoxicokineticevaluationinpreclinicalstudies.	8M	3	2
	b) Explainimportanceandapplicationsoftoxicokineticstudies.	7M	3	2
2	a)Writeindetailaboutalternativemethodsofdissolutiontestingtransport Models.	8M	2	1
	b) Writetheexperimentalmethodsforsolubility.	7M	2	1
3	a)Explainaboutthedifferent Bio-analyticalmethodsforextractionof Drugsfrombiologicalmatrices.	8M	1	3
	b) DescribetheUSFDAguidelinesforbio-analyticalmethodvalidation.	7M	1	2
4	a)Explainindetailaboutstudydesignandcrossoverstudydesignin drug Productperformance.	10M	5	2
	b) Explainaboutgenericbiologics.	5M	5	3
5	a)ExplainindetailaboutBiopharmaceuticalfactorsaffectingdrug Bioavailability.	8M	2	2
	b)ExplainIn-situandIn-vivopermeabilitytestingmethods.	7M	2	2
6	a)Writeaboutprincipleandapplicationsof: 1)Cellviabilityassays (5M) 2)Flowcytometry.(5M)	10M	4	2
	b) WriteanoteonCryopreservation.	5M	4	1
7	a) Whataretheregulatoryaspectsfollowedformetaboliteidentification?	7M	5	2
	b) Enumeratethesamplepreparationtostudymetabolitesby Human Liver Microsomes.	8M	5	4
8	Writeanoteon a) ClinicalsignificanceofBioequivalencestudies.	8M	5	1
	b) Biosimilar products.	7M	5	1

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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.

Q.No.	Question	Marks	CO	BL
1.	A. Revise the importance of HPLC in chiral analysis of Pharmaceuticals.	7	1	2
	B. Give the details of Construction and instrumentation of HPLC.	8	1	2
2	A. Categorize the different derivatization techniques in Gas chromatography.	8	2	4
	B. Evaluate the stationary and mobile phases in ion exchange chromatography.	7	2	5
3	A. Describe the instrumentation of super critical fluid chromatography.	8	3	2
	B. Outline the applications of CE-MS hyphenation techniques.	7	3	1
4	A. Illustrate the mass fragmentation pattern by giving an example.	8	4	3
	B. Explain the instrumentation involved in mass spectroscopy.	7	4	2
5	A. Outline the different factors influencing chemical shift	7	5	1
	B. Differentiate between C 13 NMR and H1 NMR	8	5	2
6	A. Explain the principle and instrumentation involved size exclusion chromatography.	8	2	2
	B. Execute the developmental techniques of capillary electrophoresis.	7	3	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
8	A. Justify the Immobilized Polysaccharide CSPs	8	1	5
	B. Describe the NOSY and COSY techniques.	7	5	2

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