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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. b) Discuss the practical aspects of preparative HPLC.	8 7	1 1	1 2
2	a) Illustrate the principle and instrumentation involved in Gas chromatography. b) Compute LC-NMR hyphenated techniques.	10 5	2 2	4 3
3	a) Describe the principle and instrumentation in supercritical fluid chromatography b) Enumerate the advantages of using crown ethers as buffer additives in capillary electrophoresis.	8 7	3 3	2 3
4	a) Compose the different applications of mass spectrometry b) Conclude LC-MS hyphenation and mass analyzers.	5 10	4 4	5 4
5	a) Design. instrumentation of NMR . b) Explain the important applications of C13 NMR	8 7	5 5	6 4
6	a) Describe the principle and instrumentation involved in affinity chromatography. b) Elaborate the different columns in gas chromatography.	10 5	2 2	2 4
7	a) Contrast the principles of FT-NMR with C13 NMR b) Demonstrate the Advances in enantiomeric separation.	7 8	5 1	4 2
8	a) Recall the Methods and modes of Capillary Electrophoresis. b) Categorize Metastable ion, Isotopic peaks, Base peak, MALDI	7 8	3 4	1 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.

Que 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 **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 Pharmacokinetic and Pharmacodynamic drug interactions.	10M	3	2
	b) Illustrate the LC-MS in bioactivity screening.	5M	3	3
2	a) 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 metabolites from biological matrices by liquid – liquid extraction.	8M	1	3
	b) Explain the EMEA guidelines for bio analytical method validation.	7M	1	2
4	a) Explain about bioavailability, purpose of bio availability studies, relative and absolute bioavailability and methods for assessing bioavailability.	10M	5	2
	b) Explain about microsomal assays.	5M	5	2
5	a) Describe drug interactions linked to transporters.	8M	3	2
	b) Explain about cytochrome P450 based drug interactions.	7M	3	2
6	a) Write about general procedure for cell culture, isolation of cells, subculture and characterisation of cells and their applications.	10M	4	2
	c) Write about the principle and applications of MTT assay.	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 Liver Microsome.	8M	5	4
8	Write a note on a) General principle and procedure involved in Protein Precipitation..	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. b) write the comparative study between herbal vs conventional drugs.	7 +8	1	1 2
2	a) Illustrate with examples bio drug-drug interactions. b) What are the different types of adulteration / substitutions of herbal drugs? Give examples for each.	7+8	4	2 2
3	a) How will you determine acid value and iodine value for an herbal cosmetic? Write its significance. b) What are causes and measures of herbal drug adulterations?	8+7	5 2	3 1
4	a) How will you determine the following toxicity in herbal formulations? i) Heavy metals ii) Pesticide residues b) Write the protocol for stability testing of natural products.	8+7	2 3	4 5
5	a) Elaborate the WHO guidelines in quality assessment of herbal drugs. b) What are the challenges in monitoring the safety of herbal medicines? Give examples.	8+7	3 4	2 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. b) How will you determine the following? i) Ash value ii) Moisture content iii) Fineness of powder.	7+8	2 5	2 2
8	a) Give the applications of spontaneous reporting scheme for bio drug adverse reactions. b) Explain Bio drug-food interactions with few examples.	8+7	4	3 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.

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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