Code. No.M032511CP

St.Pauls College of Pharmacy

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UGC Autonomous Institution

M.Pharmacy (Common for all) I Sem (PCI) (Main & Backlog) Examination Mar/ Apr 2025

Subject: Modern Pharmaceutical Analytical Techniques

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 and derive Beer lamberts law. Add a note on its limitations.	8	1	1
	b) Explain different regions in IR spectroscopy and also discuss about detectors used.	7	1	2
2	a) What are Quenchers? Discuss the different types of Quenching	5	1	2
	b) What is Chemical shift? Explain with examples different factors influencing chemical shift.	10	2	2
3	a) Categorize different peaks observed in MS and explain isotope peaks with examples.	7	3	4
	b) Enlist the different Ionizers used in MS and explain any three in detail.	8	3	2
4	a) Explain the pumps and detectors used in HPLC.	8	4	2
	b) Discuss HPTLC and its applications.	7	4	2
5	a) Write the Principle and working conditions of paper Electrophoresis	8	5	3
	b) Classify the types of crystals and add a note on applications of X ray diffraction	7	5	3
6	a) Enlist the different electrodes used in Potentiometry and explain the construction and working of any one electrode.	8	6	1
	b) Write the Principle of TGA, What factors are responsible for affecting TGA results and write the applications of TGA.	7	6	3
7	a) Explain the sampling techniques in IR spectroscopy	7	1	2
	b) Create MS Spectrum for any two compounds and explain its peaks.	8	3	6
8	a) Add a note on Shielding and deshielding	8	2	1
	b) Enlist and explain the detectors used in Gas chromatography	7	4	1

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M. Pharmacy (Pharmaceutics) I Semester (PCI) (Main & Backlog) Examination Mar/Apr 2025

Subject: Drug Delivery System & MPH102T

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) Explain about Customized drug delivery systems	8	1	2
	b) Classify Polymers and write examples	7	1	2
2	a) Describe the mechanisms of various Osmotic activated Drug Delivery Systems	8	2	2
	b) Explain the principle involved in the feedback drug delivery systems	7	2	2
3	a) Describe briefly about theories of mucoadhesion	8	2	2
	b) Explain the parameters that influence the penetration of drugs across Buccal membrane	7	2	2
4	a) Explain anatomy of the Blood brain barrier.	8	2	2
	b) Explain Buoyant gastro-retentive drug delivery systems	7	3	2
5	a) Classify transdermal drug delivery systems based on the Design	8	5	3
	b) Explain how the Penetration enhancers work in transdermal drug delivery systems	7	5	2
6	a) Explain the barriers of Peptide delivery	8	5	2
	b) Describe various methods to deliver macromolecules	7	5	2
7	a) Explain the mucosal delivery of vaccines	8	6	2
	b) What difficulties faced by vaccines while delivering through transdermal drug delivery	7	6	1
8	a) Explain about Telepharmacy and its significance	8	2	2
	b) Describe about 3D printing of pharmaceuticals	7	2	2

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M.Pharmacy (Pharmaceutics) I Semester (PCI) (Main & Backlog) Examination Mar/ Apr 2025

Subject: MODERN PHARMACEUTICS & MPH103T

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) Discuss the manufacturing and evaluation of small-volume parenterals b) Define drug stability and explain the role of kinetics in stability studies with appropriate examples	7 8	1 1	2 2
2	a) Explain the concept of optimization parameters in pharmaceutical formulation b) Define factorial design and explain its importance in pharmaceutical formulation.	7 8	1 1	1 1
3	Explain the purpose and significance of the Validation Master Plan in pharmaceutical manufacturing.	15	2	2
4	a) Outline the objectives of cGMP b) Explain the role of production management in ensuring quality in pharmaceutical manufacturing.	5 10	3 3	1 2
5	Critically evaluate the factors affecting tablet compression and consolidation in pharmaceutical manufacturing.	15	4	5
6	How does the design and integration of Chi-square, Student's t-test, and ANOVA enhance pharmaceutical data analysis?	15	5	5
7	a) Show how effective personal relationships influence team performance in pharmaceutical organizations. b) Demonstrate the use of Peppas equation in analyzing drug release mechanisms.	8 7	3 5	3 3
8	a) Outline how variations in force distribution influence the mechanical properties of compressed tablets. b) Illustrate the relationship between government regulations and the implementation of qualification protocols (DQ, IQ, OQ, PQ) in pharmaceutical facilities.	7 8	4 2	4 4

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M.Pharmacy (Pharmaceutics) I Semester (PCI) (Main &Backlog) Examination Mar/Apr 2025

Subject: Regulatory Affairs & MPH104T

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

PART- A

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

Q.No.	Question	Marks	CO	BL
1	a)Eloborate Post marketing surveillance on pharmaceuticals b) Write a note on CFR (Code of Federal Register).	8 7	2 2	4 2
2	a) Mention the multidisciplinary guidelines related to international conference on harmonization b) Explain the regulatory requirements of EU in drug approval process	8 7	1 1	1 2
3	a) Explain in detail about Non Clinical Drug Development b) Discuss in detail the steps involved in Abbreviated New Drug regulatory approval process.	8 7	2 2	2 2
4	a) Outline the steps involved in clinical trial protocol. b) Discuss the constitution and Functions of Independent Ethics Committee.	10 5	2 2	6 2
5	a) Write a note on Scale up process and its significance b) Write a note on Regulatory requirement of ANDA generic drug approval in US	8 7	1 1	2 2
6	a) Write a note on Industry and FDA liaison b) Describe Q8, Q9 and Q10 ICH Quality guidelines.	7 8	2 2	2 2
7	Discuss about (a) Investigation of Medicinal Products Dossier (IMPD) (b) Investigation brochure.	8 7	1 1	2 2
8	a) Write a note on Pharmacovigilance safety monitoring. b) Write a note on HIPAA.	8 7	1 1	2 2

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M.Pharmacy (Pharmaceutics) I Semester (PCI) (Supple) Examination Jul/August 2024

Subject & Code: Regulatory Affairs MPH104T

Max.Marks: 75

Time: 3 Hours

PART- A

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

Q.No.	Question	Marks	CO	BL
1	a) Describe ANDA regulatory approval process.	9	4	2
	b) Explain Code of Federal Regulation.	6	2	2
2	a) Describe the regulatory requirements for approval of biologics.	9	2	2
	b) What are the regulations for novel therapies obtaining NDA approval?	6	4	1
3	a) Describe the regulatory requirements of TGA.	10	3	2
	b) Explain industry and FDA liaison.	5	2	2
4	a) Explain Investigational Medicinal product dossier	8	5	2
	b) Write a note on Investigator Brochure (IB).	7	1	3
5	a) Describe clinical trial protocol and how to develop it.	8	5	2
	b) Write about HIPAA role in clinical study process.	7	4	3
6	a) Explain in-vitro drug product performance.	8	5	2
	b) Describe Post marketing surveillance.	7	6	2
7	a) Explain regulations for Combination products.	9	2	2
	b) Write a note on CTD modules.	6	1	3
8	a) Describe Pharmacovigilance safety monitoring in clinical trials.	10	5	2
	b) Explain Chemistry, Manufacturing and control (CMC).	5	2	2

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M.Pharmacy (Pharmaceutics) I Semester (PCI) (Supple) Examination Jul/August 2024

Subject: Modern Pharmaceutics MPH103T

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) List out the methods used for determination of drug-excipients interactions and discuss any three methods in detail with examples b) Formulation and evaluation methods for Parenteral dosage form.	8+7	1	1 2,5
2	a) Explain various optimization techniques used for pharmaceutical formulations. b) Assess about factorial design.	10+5	1	2 5
3	a) Write the ICH guidelines for calibration and validation of equipment? b) Ilustrate the terms DQ, IQ, OQ and PQ?	8+7	2	2 4
4	a) Design and development in layout of buildings, services in industries according to GMP. b) Describe the total quality management?	10+5	3	1 6
5	a) Write a note on inventory management and production control management. b) Justify the sale forecasting and budget planning in industries?	8+7	3	2 5
6	a) Define compaction profile? Explain the phases of compaction profile with a suitable examples b) Describe in detail about physics of tablet compression	7+8	4	2 5
7	a) Discuss about the pharmacokinetic parameters required for determination of bioavailability b) Outline the methods for enhancement of aqueous solubility of drugs	8+7	4,5	2 5
8	Write a note on a) Heckle plots b) ANOVA test C) Higuchi and Peppas plot	5+5+5	5	2

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Code. No.M082411CP

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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	a) What is chemical shift and write the factors effecting chemical shift	10	2	3
	b) Explain spin-spin coupling and give the applications of 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 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
	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	a) Define Atomic Absorption Spectroscopy and write the principle and instrumentation.	7	1	1
	b) Write a note on Quenching and give applications of fluorescence spectrophotometer.	8	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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Code. No.M022411CP

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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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Code. No. M6022412

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M.Pharmacy (Pharmaceutics) I Semester (PCI) (Main) Examination Feb/March 2024

Subject: DRUG DELIVERY SYSTEMS MPH102T

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 physico chemical factors influencing the controlled release of drugs	8	1	1
	b)Classify the polymers with examples and state its pharmaceutical applications	7	1	2
2	a) Differentiate the customized drug delivery systems from conventional dosage forms and illustrate the customized delivery with one example	10	1	2
	b) Outline the bioelectronic medicines and its applications	5	1	2
3	a) Distinguish various types of activation modulated drug delivery systems	8	2	2
	b)Explain feedback regulated drug delivery systems with examples	7	2	2
4	a)State the needs of buccal drug delivery systems	4	3	1
	b)Demonstrate the development of buccal drug delivery systems	6	3	2
	c)Appraise the evaluation of buccal drug delivery systems	5	3	5
5	a)Categorize different barriers for drug permeation in ocular cavity and how do you overcome	9	4	4
	b)Elaborate the formulation of Ocuserts	6	4	3
6	a)Discuss the different types of Trans dermal drug delivery (TDDS) and its formulation	8	5	2
	b)Describe the evaluation of TDDS	7	5	2
7	a)Execute the challenges faced in protein drug delivery	5	7	3
	b)Discuss the formulation and evaluation of drug delivery systems of macromolecules	10	7	2
8	a) Describe the single shot vaccines	8	6	2
	b) Appraise the mucosal delivery of vaccines	7	6	5

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M.Pharmacy (Pharmaceutics) I Semester (PCI) (Regular) Examination Feb/March 2024

Subject: Modern Pharmaceutics – MPH103T

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) Discuss the different orders of reaction and their applications?	7	1	1
	b) Formulation and evaluation methods for SMEDDS.	8	1	2,5
2	a) Explain various parameters of optimization used for pharmaceutical formulations.	10	1	2
	b) Assess about Response surface method.	5	1	5
3	a) Discuss WHO good manufacturing practices in a pharmaceutical Industry?	8	2	2
	b) Ilustrate the validation of tableting process?	7	2	3
4	a) Design and development in layout of buildings, services in industries according to cGMP.	8	3	5
	b) Explain different elements of Total Quality Management.	7	3	6
5	a) Give an account on various approaches for inventory management and control.	8	3	2
	b) Justify the budget planning in industries?	7	3	5
6	a) Explain the types of compaction profiles	7	4	1
	b) Justify the effect of friction during tablet compression	8	4	5,6
7	a) Describe the comparison of dissolution profiles of dosage forms using similarity and difference factors.	8	4	3
	b) Outline the solubility enhancement techniques.	7	5	4
8	Write a note on			
	a) Heckel Plots	5	5	2
	b) Students T-test	5	5	
	C) Chi square test	5	5	

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M.Pharmacy (Pharmaceutics) I Semester (PCI) (Supple) Examination Jul/August 2024

Subject & Code: Regulatory Affairs MPH104T

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) Describe ANDA regulatory approval process.	9	4	2
	b) Explain Code of Federal Regulation.	6	2	2
2	a) Describe the regulatory requirements for approval of biologics.	9	2	2
	b) What are the regulations for novel therapies obtaining NDA approval?	6	4	1
3	a) Describe the regulatory requirements of TGA.	10	3	2
	b) Explain industry and FDA liaison.	5	2	2
4	a) Explain Investigational Medicinal product dossier	8	5	2
	b) Write a note on Investigator Brochure (IB).	7	1	3
5	a) Describe clinical trial protocol and how to develop it.	8	5	2
	b) Write about HIPAA role in clinical study process.	7	4	3
6	a) Explain in-vitro drug product performance.	8	5	2
	b) Describe Post marketing surveillance.	7	6	2
7	a) Explain regulations for Combination products.	9	2	2
	b) Write a note on CTD modules.	6	1	3
8	a) Describe Pharmacovigilance safety monitoring in clinical trials.	10	5	2
	b) Explain Chemistry, Manufacturing and control (CMC).	5	2	2

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