Code no:M6022414

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

Subject: 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) Write a brief note on the importance of documentation in Pharmaceutical industry with examples.	7	1	3
	b) Explain Generic drugs product development.	8	4	2
2	a) list out the regulatory requirements for approval of API.	9	2	1
	b) Explain the process for US registration of foreign drugs.	6	3	2
3	a) Describe the regulatory requirements of EU.	10	3	2
	b) Compare CTD and eCTD.	5	1	4
4	a) Write a note on Global Submission of IND.	8	4	3
	b) Explain Investigational Medicinal product dossier (IMPD).	7	5	2
5	a) Describe the constitution and role of Institutional review board.	8	5	2
	b) How do you develop clinical trial protocol.	7	5	4
6	a) Explain Hatch-Waxmann act and its amendments.	8	1	2
	b) Describe NDA approval process.	7	4	2
7	a) Write a note on ICH Quality guidelines.	10	1	4
	b) Write a note on Investigator Brochure (IB).	5	2	4
8	a) Describe HIPAA and its role.	9	5	2
	b) Explain Informed consent process.	6	5	2

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Code. No M6022413.

St.Pauls College of Pharmacy

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Recognition of College under Section 2(f) of the UGC Act 1956,
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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? b) Formulation and evaluation methods for SMEDDS.	7 8	1 1	1 2,5
2	a) Explain various parameters of optimization used for pharmaceutical formulations. b) Assess about Response surface method.	10 5	1 1	2 5
3	a) Discuss WHO good manufacturing practices in a pharmaceutical Industry? b) IIustrate the validation of tableting process?	8 7	2 2	2 3
4	a) Design and development in layout of buildings, services in industries according to cGMP. b) Explain different elements of Total Quality Management.	8 7	3 3	5 6
5	a) Give an account on various approaches for inventory management and control. b) Justify the budget planning in industries?	8 7	3 3	2 5
6	a) Explain the types of compaction profiles b) Justify the effect of friction during tablet compression	7 8	4 4	1 5,6
7	a) Describe the comparison of dissolution profiles of dosage forms using similarity and difference factors. b) Outline the solubility enhancement techniques.	8 7	4 5	3 4
8	Write a note on a) Heckel Plots b) Students T-test C) Chi square test	 5 5 5	 5 5 5	 2

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Code. No. M6022412

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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