

GUJARAT TECHNOLOGICAL UNIVERSITY

BE - SEMESTER-VII (NEW) EXAMINATION – SUMMER 2024

Subject Code:3173621

Date:01-06-2024

Subject Name:Drug Delivery, Biotechnology, Validation Requirements and Regulatory Affairs

Time:02:30 PM TO 05:00 PM

Total Marks:70

Instructions:

1. Attempt all questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.
4. Simple and non-programmable scientific calculators are allowed.

		Marks
Q.1	(a) Define the term: CAPA	03
	(b) Write a note on formulation of controlled release dosage forms.	04
	(c) Define and explain liposome with neat labelled diagram.	07
Q.2	(a) What are aerosols? Explain the parts of aerosol container.	03
	(b) Discuss Ophthalmic drug delivery system in detail.	04
	(c) Define Validation and describe Process validation in detail.	07
	OR	
	(c) What is GMP? Importance of GMP, where it is applicable.	07
Q.3	(a) What is Regulatory affairs and scope of Regulatory affairs in pharmaceutical industry	03
	(b) Brief generic drug in detail.	04
	(c) Explain with suitable diagram:	07
	(i) Aseptic operation and containment in fermentation	
	(ii) Sterilization of air in fermentation	
	OR	
Q.3	(a) Define the term: Immobilized enzymes	03
	(b) Describe the bioreactors used in solid state fermentation with diagrams.	04
	(c) Write a note on Genetic engineering principles & techniques and its application in medicines	07
Q.4	(a) Define the term: nanoparticles	03
	(b) What are radiopharmaceuticals? Write its applications.	04
	(c) Explain the types of emulsions in detail.	07
	OR	
Q.4	(a) Explain different Types of ICH guidelines and also explain quality guideline in detail.	03
	(b) Define Cosmetics. Write a brief note on cosmetic products.	04
	(c) What is Schedule Y? What are the requirements and guidelines needed for Schedule Y?	07

- Q.5 (a)** Write a note on Drug Master File. **03**
- (b)** What is Transmucosal drug delivery system and explain briefly its Classifications. **04**
- (c)** Differences between NDA and ANDA? Brief about CTD dossier modules? **07**

OR

- Q.5 (a)** Write a note on Drug Price Control Order and mention the importance of it in Pharmaceutical industries. **03**
- (b)** Write briefly the formulation design of Transdermal drug delivery System. **04**
- (c)** Write a short note on schedule M and brief about part 1 of schedule M? **07**
