

GUJARAT TECHNOLOGICAL UNIVERSITY**BE - SEMESTER-VII (NEW) EXAMINATION – WINTER 2023****Subject Code:3173621****Date:19-12-2023****Subject Name: Drug Delivery, Biotechnology, Validation Requirements and Regulatory Affairs****Time: 10:30 AM TO 01:00 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) What is Schedule Y drugs?	03
	(b) Differentiate Submerged liquid fermentation & Solid state fermentation.	04
	(c) Define and explain liposome with neat labelled diagram.	07
Q.2	(a) Define: Radiopharmaceuticals.	03
	(b) Write a note on formulation of controlled release dosage forms.	04
	(c) What is ICH guideline? Types of ICH guidelines, Brief quality guideline.	07
	OR	
	(c) What is Schedule H drugs? What are the requirements and guidelines needed for Schedule H?	07
Q.3	(a) What is Regulatory affairs and scope of Regulatory affairs in pharmaceutical industry?	03
	(b) Define and explain Restriction enzyme.	04
	(c) Describe Glutamic acid manufacturing by fermentation technique.	07
	OR	
Q.3	(a) What is sterilization?	03
	(b) Explain Recombinant DNA technology.	04
	(c) Explain (1) NDA, (2) ANDA	07
Q.4	(a) What is eCTD and enlist its benefits.	03
	(b) Define sustained release drug delivery system with its advantages.	04
	(c) Describe Liposome with a neatly labeled diagram.	07
	OR	
Q.4	(a) What are Cosmetics?	03
	(b) Explain the components of Transdermal drug delivery system.	04
	(c) Describe Aerosol with a neatly labeled diagram.	07
Q.5	(a) Differentiate Sustained release and Controlled release drug dosage forms.	03
	(b) Write briefly the formulation design of Transmucosal drug delivery System.	04
	(c) Describe Process validation in detail.	07

OR

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| Q.5 | (a) Write advantages of controlled & sustained drug delivery system. | 03 |
| | (b) Write a note on DPCO and its importance in Pharmaceutical Industries | 04 |
| | (c) What are emulsions? Explain the roles of emulsifying agents. Give its types. | 07 |
