

GUJARAT TECHNOLOGICAL UNIVERSITY**BE- SEMESTER-VIII (NEW) EXAMINATION – WINTER 2020****Subject Code:2183601****Date:19/01/2021****Subject Name:Drug Delivery, Biotechnology & Validation Requirement****Time:02:00 PM TO 04:00 PM****Total Marks: 56****Instructions:**

1. Attempt any FOUR questions out of EIGHT questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

		MARKS
Q.1	(a) Write a note on Radiopharmaceuticals.	03
	(b) Discuss the Schedule-M guidelines for process validation	04
	(c) Describe the components of aerosol system with a neat-labeled diagram.	07
Q.2	(a) Write a note on Drug Master File.	03
	(b) What are cosmetic products? Write a brief note on cosmetic products.	04
	(c) Explain genetic engineering and the process involved in it.	07
Q.3	(a) Define DPCO and write a brief note on it.	03
	(b) Write the components of Sustained Release Drug Delivery System	04
	(c) Explain in detail Ophthalmic drug delivery system	07
Q.4	(a) Write notes on (1). Informed consent, (2). Ethics committee.	03
	(b) Write the components of Transdermal Drug Delivery System (TDDS)	04
	(c) Describe Liposome in detail with proper diagram.	07
Q.5	(a) Draw the basic design of fermenter. Label it properly.	03
	(b) What is Preformulation. Explain the steps involved in pre formulation of SRDDS (sustained release drug delivery system).	04
	(c) Describe NDA & ANDA	07
Q.6	(a) Write a note on the aseptic operation & containment in a fermentation process.	03
	(b) What are Sustained release & Controlled release dosage forms. Write the differences between these two dosage forms.	04
	(c) What is Schedule Y? What are the requirements & guidelines needed for schedule Y	07
Q.7	(a) Write a note on recombinant DNA technology	03
	(b) Define aerosols and explain its evaluation tests in detail	04
	(c) Describe: Sterilization of fermenter & sterilization of air supply in a fermenter with suitable diagrams	07
Q.8	(a) Write a note on restriction enzyme.	03
	(b) What are emulsions? Explain the role of emulsifying agent.	04
	(c) Describe solid state fermentation. Compare solid state fermentation (SSF) & submerged liquid fermentation (SLF)	07
