

Seat No.: \_\_\_\_\_

Enrolment No. \_\_\_\_\_

**GUJARAT TECHNOLOGICAL UNIVERSITY**

**BE - SEMESTER-VIII (NEW) - EXAMINATION – SUMMER 2018**

**Subject Code: 2183601**

**Date: 30/04/2018**

**Subject Name: Drug Delivery, Biotechnology & Validation**

**Requirement(Department Elective – IX)**

**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.

			MARKS
Q.1*	(a)	Describe how sterilization is effected in fermenter.	03
	(b)	Discuss the Schedule-M guidelines for process validation	04
	(c)	Explain the importance of particle size in pre formulation development. What are the methods to determine particle size. Explain any two in detail.	07
Q.2	(a)	Define “Liposome”. What are the uses of Liposome?	03
	(b)	Discuss the role of restriction enzyme in recombinant DNA technology.	04
	(c)	Compare solid state fermentation (SSF) & submerged liquid fermentation (SLF).	07
<b>OR</b>			
	(c)	Define the role of agitator. What are the different types of agitators used in fermentation?. Discuss any two in detail.	07
Q.3	(a)	Describe “Drug Master File”	03
	(b)	Describe Transmucosal and Nano particle drug delivery.	04
	(c)	Write a detailed note on the requirements under schedule-Y for phase-I, II, III & IV trials.	07
<b>OR</b>			
Q.3	(a)	Define Emulsion. What are the classifications of emulsion?	03
	(b)	Discuss the merits & demerits of sustained release dosage forms.	04
	(c)	Define Aerosol. Elaborate its advantages & disadvantages.	07
Q.4	(a)	Draw the basic design of fermenter. Label it properly.	03
	(b)	Explain genetic engineering and the process involved in it.	04
	(c)	Discuss the NDA approval process with flow chart.	07
<b>OR</b>			
Q.4	(a)	Define “DPCO”. Write a brief note on it.	03
	(b)	Describe Hatch Waxman amendments in ANDA filing.	04
	(c)	Discuss ANDA & NDA in detail.	07
Q.5	(a)	What is transdermal drug delivery system?. Briefly explain the basic components.	03
	(b)	Describe (1). Ethics committee, (2). Informed consent	04
	(c)	Write a detailed note on Immobilized enzyme.	07
<b>OR</b>			
Q.5	(a)	What do you mean by NDA (New drug Application) and what type of data is submitted in it?	03
	(b)	Explain the advantages & disadvantages of Radiopharmaceuticals.	04
	(c)	What are the major components of Fermentation process?	07

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