

GUJARAT TECHNOLOGICAL UNIVERSITY**BE- SEMESTER-VII (NEW) EXAMINATION – WINTER 2020****Subject Code:2173602****Date:19/01/2021****Subject Name:Process Technology of Drugs & Intermediates****Time:10:30 AM TO 12:30 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) Define: (1). Validation, (2). Qualification, (3). GMP	03
	(b) Define chiral auxiliary. Describe the use of chiral auxiliary with a schematic diagram. Write one example of the use of chiral auxiliary.	04
	(c) List out the techniques in identifying exothermicity & gas generation. Briefly explain them. Illustrate use of calorimetry in designing safe scale up process with two examples.	07
Q.2	(a) What are super critical solvents? Give an example. What are the advantages & disadvantages of super critical solvents?	03
	(b) Describe the working of simulated bed chromatography with diagram. What are the advantages & disadvantages?	04
	(c) What are the classifications of Enzymes? Write in detail about Lipases & Esterases with suitable examples of reactions catalyzed by them.	07
Q.3	(a) Write a note on “sources of enzyme”	03
	(b) Discuss Ultra filtration & Microfiltration	04
	(c) Explain the different types of Process validations. What are the types of validation documents?	07
Q.4	(a) Define process safety. Write a note on the types of hazards	03
	(b) Explain Marckwald principle & Reciprocal resolutions. Illustrate with example.	04
	(c) Describe the need, different types of “Qualifications” in Pharmaceutical industries. Explain qualification protocol.	07
Q.5	(a) Define adsorption. Write the theory & factors affecting adsorption.	03
	(b) Describe process safety failures and the consequences.	04
	(c) Write briefly the factors to be considered while selecting filtration equipment. Describe any two filtration equipments with neat diagrams.	07
Q.6	(a) What are the selection criteria for resolving agents. Give one example of the use of resolving agent.	03
	(b) Describe residual solvents? Write a note on the classification of solvents by risk assessment.	04
	(c) Discuss in detail the optimization of process. Illustrate with suitable examples.	07

- Q.7** (a) Write a brief account on “Regulation of Enzyme activity” **03**
(b) Define “reagent”? Explain the properties to be considered while selecting a reagent. **04**
(c) List out the factors to be considered while choosing solvent and explain them. **07**
- Q.8** (a) Write a note on (1) Ion exchange chromatography, (2). Gel filtration chromatography **03**
(b) Write a note on Phase transfer catalyst. What are the factors to be considered while choosing a Phase Transfer Catalyst (PTC) & how selectivity in PTC can be achieved? **04**
(c) Describe two methods of resolution of racemates by direct crystallization with suitable examples. **07**

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