

GUJARAT TECHNOLOGICAL UNIVERSITY

BE - SEMESTER– VII (New) EXAMINATION – WINTER 2019

Subject Code: 2173602

Date: 23/11/2019

Subject Name: Process Technology of Drugs & Intermediates

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) Define Process safety. Briefly explain the types of hazards	03
	(b) Describe Simulated Bed Chromatography with a schematic diagram.	04
	(c) Describe the resolution of Racemates by (1). Direct crystallization method, (2). Preferential crystallization method with example and schematic diagrams.	07
Q.2	(a) Why Good manufacturing Practices (GMP) are to be followed in Pharma Industries? Where these guide lines are applicable? What are the importance of GMP	03
	(b) Describe the steps which are to be taken for optimizing reactions	04
	(c) Briefly discuss the techniques for identifying exothermicity & gas generation. Illustrate the use of calorimetry with three examples.	07
OR		
	(c) Discuss about (1). Choosing a Phase transfer catalyst (PTC), (2). How selectivity in PTC can be achieved. Illustrate the advantages of using PTC in any two organic synthesis	07
Q.3	(a) Why enzymes are preferred as catalyst? Describe the regulation of enzymes	03
	(b) Define Chiral auxiliary. With a schematic diagram, illustrate the use of Chemical Auxillary. Give one example of the use of Chiral auxillary	04
	(c) What are the factors to be considered while choosing a solvent. Briefly describe them.	07
OR		
Q.3	(a) Discuss about Marckwald principle & Reciprocal resolution with example	03
	(b) Discuss "Residual solvents". Write a note on classification of solvents by risk assessment.	04
	(c) Describe, (1). Adulterated drug, (2). Deviation investigation, (3). CAPA	07
Q.4	(a) Write a note on Supercritical liquid as solvent	03
	(b) Discuss the steps to be taken for optimizing the mesylation of Propargylic alcohol	04
	(c) Write a note on classifications of Enzymes. Discuss in detail the Lipases & Esterases and their catalytic reactions.	07
OR		
Q.4	(a) Write a note on Enzymes & their sources.	03
	(b) Define "Reagent". List out the factors to be considered while selecting reagent.	04
	(c) Explain in detail the factors affecting the enzyme activity	07
Q.5	(a) Briefly describe Adsorption & factors affecting adsorption.	03
	(b) Explain in detail Chromatography as a separation technique.	04
	(c) Describe (1). cGMP violations (2). Qualifications in GMP	07
OR		

- Q.5 (a) Briefly describe Reverse osmosis, Microfiltration & Ultra filtration separation processes. **03**
- (b) What are the principle factors to be considered while selecting filtration equipment. Explain the working of rotary drum filter & leaf filter with a suitable diagram. **04**
- (c) Why documentation is important in GMP? List out the important documents required under GMP. Write detailed notes on Process validation. **07**

www.FirstRanker.com