Seat No.: _____ Enrolment No.

GUJARAT TECHNOLOGICAL UNIVERSITY

BE - SEMESTER–VII (NEW) EXAMINATION – WINTER 2018

Subject Code: 2173602 **Date: 15/11/2018**

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)**	Write a brief account on "Regulation of Enzyme activity"	**03**
	(b)	List out the steps for optimization of process. Describe any two steps with suitable example.	**04**
	(c)	List out the different types of documents to be maintained in GMP. Describe any four of them in detail.	**07**
Q.2	**(a)**	List out the factors to be considered while choosing a Phase Transfer Catalyst (PTC) & how selectivity in PTC can be achieved?	**03**
	(b)	Define "Process Safety". Briefly discuss the types of hazard to be considered from reactivity of compounds.	**04**
	(c)	List out the factors to be considered when selecting filtration equipment. Describe any two filtration equipment with neat diagrams.	**07**
		OR	
	(c)	Describe with suitable neat diagrams: (a). Column Chromatography, (b). Ion exchange Chromatography, (c).Gel filtration chromatography	**07**
Q.3	**(a)**	Briefly discuss the Process safety failure consequences.	**03**
	(b)	Write a note on Simulated Bed Chromatography. What are its advantages?	**04**
	(c)	Describe the factors influencing the enzyme activity.	**07**
		OR	
Q.3	**(a)**	Discuss Ultra filtration & Microfiltration	**03**
	(b)	Define Adsorption. Discuss briefly about the factors affecting adsorption.	**04**
	(c)	What are the classifications of Enzymes? Write in detail about Lipases & Esterases with suitable examples of reactions catalyzed by them.	**07**
Q.4	**(a)**	Define "Adulterated Drug". Write a note on the importance of GMP in Pharmaceutical industries.	**03**
	(b)	Write a brief note on Marckwald principle & Reciprocal resolutions with example	**04**
	(c)	Briefly explain the techniques for identifying exotherm & gas generation. Describe with two suitable examples for the Calorimetry use in designing safe scale up process.	**07**
		OR	
Q.4	**(a)**	Write a note on super critical liquid as solvent	**03**
	(b)	What is a "reagent"? Discuss the properties to be considered while selecting a reagent.	**04**
	(c)	Describe two methods of resolution of racemates by direct crystallization with suitable examples.	**07**
Q.5	**(a)**	What are the requirements of Chiral auxillaries? Write the schematic representation of the use of Chiral Auxillary.	**03**
	(b)	Define "Residual Solvents" in drug substance. Briefly discuss the classifications of residual solvent by risk assessment.	**04**

	(c)	Define "Qualification". Explain the different types of qulifications and their need in Pharmaceutical industries. List out the important contents in Qualification protocol.	**07**

OR

Q.5	**(a)**	What are the selection criteria for resolving agents. Give one example of the use of resolving agent.	**03**
	(b)	List out the factors in choosing a solvent. Explain any two factors in detail.	**04**
	(c)	Define "Validation". Explain the different types of Process validations. What are the types of validation documents?	**07**

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