Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

BE - SEMESTER–VII(NEW) • EXAMINATION – WINTER 2016

Subject Code:2173602 **Date:18/11/2016**

Subject Name:Process Technology of Drugs & Intermediates(Department Elective - VII)

Time:10.30 AM to 1.00 PM **Total Marks: 70**

Instructions:

1. **Attempt all questions.**
2. **Make suitable assumptions wherever necessary.**
3. **Figures to the right indicate full marks.**

Q.1 **(a)** Define GMP(Good Manufacturing Practices). What are the basic principles on which the GMP guidelines are based? **07**

(b) Discuss the importance of using solvents in detail. **07**

As per ICH guidelines, indicate the class of solvent as below

Solvent	Class As per ICH guideline
Acetone	
1,2-Dichloroethane	
Ethanol	
Methanol	
2-Methyl-Tetrahydrofuran	
Benzene	
Dimethylformamide	

Q.2 **(a)** Discuss implications of process safety failure in detail with at least two examples? **07**

(b) What are DQ, IQ, OQ, CQ & PQ and why are they required in Pharmaceutical industry as part of GMP ? **07**

OR

(b) What are the different types of process validations? Briefly explain each one of them? **07**

Q.3 **(a)** List and write in detail about the different classes of enzymes? **07**

(b) Describe Adsorption technique in detail. Mention its principle, different types of adsorptions, factors affecting adsorption. **07**

OR

Q.3 **(a)** **(i).** Fill in the following w.r.t rate of reaction with polarity **05**

1.In SN2 reaction, where there is charge dispersion in the transition state the reaction rate ---------- with ---------- in solvent polarity

2.In SN2 reaction, where there is charge separation in transition sate the reaction

rate ---------- with ---------- in solvent polarity
3. In SN2 reaction, where there is charge destruction in the transition state the reaction rate ---------- with ---------- in solvent polarity
4. In SN1 reaction, where there is charge separation in the transition state the reaction rate ---------- with ---------- in solvent polarity
5. In SN1 reaction, where there is charge dispersion in the transition state the reaction rate ---------- with ---------- in solvent polarity

(ii). How is selectivity achieved when using Phase Transfer Catalyst (PTC). **02**

(b) Describe in detail about various large scale chromatography techniques used in Pharmaceutical industries. Mention their basis of separation **07**

Q.4 **(a)** Explain Michealis Menton kinetics in enzyme catalysis **07**

(b) (i).What is Simulated Moving Bed Chromatography (SMB)? Discuss the advantage & disadvantage of SMB over HPLC **04**

(ii). What is Chromatography? Describe paper chromatography **03**

OR

Q.4 **(a)** What factors influence the enzyme activity? Describe them in detail. **07**

(b) Describe in detail about the various separation techniques in Pharmaceutical industries. Mention their basis of selection **07**

Q.5 **(a)** What factors are considered when choosing a reagent? Explain in detail **07**

(b) Describe two API syntheses in detail where use of PTC is advantageous. **07**

OR

Q.5 **(a)** List different types of documents required under GMP and discuss any three of them? **07**

(b) Describe the following with suitable examples: **07**

i. Runaway reactions,
ii. Use of Calorimetry in addressing reaction safety ,
iii. Factors affecting enzyme activity?

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