Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B. PHARM - SEMESTER–VII • EXAMINATION – WINTER -2022

Subject Code: 2270001 Date: 22/12/2022

Subject Name: Dosage Form Design I

Time: 10:30am to 01:30pm Total Marks: 80

Instructions:

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

Q.1	**(a)**	What is a preformulation study? Describe theoretical aspects for determining solubility and permeability of drug and its application.	**06**
	(b)	Explain effect of physical properties of drug like physical form, particle size and shape on formulation, stability and bioavailability.	**05**
	(c)	Discuss various drug degradation pathways and discuss oxidation in detail.	**05**
Q.2	**(a)**	Discuss the regulatory requirements for conduction of bio-equivalence studies.	**06**
	(b)	Define prodrug. Give its applications for improving stability of drug.	**05**
	(c)	Enlist excipients used in Solid dosage form. Explain in details about Cellulose derivatives.	**05**
Q.3	**(a)**	Enumerate factors affecting gastro intestinal absorption. Discuss in detail effect of gastric empting time on drug absorption.	**06**
	(b)	What do you mean by polymer? Write a note on polymers used in different dosage forms with examples.	**05**
	(c)	Write a note on matrixing and bracketing in stability study.	**05**
Q.4	**(a)**	Describe the effect of containers and closures on stability of pharmaceuticals.	**06**
	(b)	Discuss the factors affecting on stability of the drug.	**05**
	(c)	Explain various methods used for enhancement of bioavailability.	**05**
Q.5	**(a)**	Define relative and absolute bioavailability. Discuss plasma level time studies for measurement of bioavailability.	**06**
	(b)	What is bioequivalence? Write a short note on Latin-square cross-over design.	**05**
	(c)	Define BCS and BDDCS. Discuss theory of dissolution.	**05**
Q. 6	**(a)**	Enumerate different types of transport mechanism. Explain facilitated transport in detail.	**06**
	(b)	Discuss storage conditions for stability testing as per ICH guidelines.	**05**
	(c)	Describe the influence of BBB and CSF barriers on distribution of drugs	**05**
Q.7	**(a)**	Discuss Noyes Whitney equation for rate of dissolution. Discuss USP type II apparatus for dissolution.	**06**
	(b)	Classify methods for dissolution profile comparison and discuss model independent method in brief.	**05**
	(c)	What is the importance of protein binding of drugs? Describe tissue binding of drugs in detail.	**05**

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