Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM - SEMESTER– 7 EXAMINATION – SUMMER-2024

Subject Code: 2270001 **Date: 30/04/2024**

Subject Name: Dosage form Design I

Time: 02.30 p.m. to 5.30 p.m. **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 BCS classification? How does it affect the development of dosage form?	**06**
	(b)	Define Half-life and Shelf life. Discus about international climatic zones as per ICH guideline	**05**
	(c)	Define Bioequivalence. Explain the significance of Latin square cross over design.	**05**
Q.2	**(a)**	Enlist various methods for measurement of bioavailability. Discuss any one in detail.	**06**
	(b)	Discuss pH –Partition hypothesis along with its assumptions.	**05**
	(c)	Discuss the influence of container and closures on product stability.	**05**
Q.3	**(a)**	Discuss stability testing of new drug substances and products as per ICH guideline.	**06**
	(b)	Write a short note on “Plasma Protein Binding”.	**05**
	(c)	What are similarity factor and dissimilarity factor? How are they calculated and explain its significance.	**05**
Q.4	**(a)**	What is a Preformulation study? Describe theoretical aspects for determining solubility and permeability of drug and its application.	**06**
	(b)	Discuss the effect of containers and closures on stability of pharmaceuticals.	**05**
	(c)	Discuss in detail volume of distribution.	**05**
Q.5	**(a)**	Classify the polymers. Discuss in brief about polymer properties.	**06**
	(b)	Define i) Bioavailability ii) Cmax iii) tmax iv) Overage v) Mean Kinetic Temperature	**05**
	(c)	Write a note on drug clearance.	**05**
Q. 6	**(a)**	Define relative and absolute bioavailability. Discuss plasma level time studies for measurement of bioavailability.	**06**
	(b)	Write a note on Biodegradable polymers.	**05**
	(c)	Explain accelerated stability study as per ICH guidelines.	**05**
Q.7	**(a)**	Enlist various transport mechanisms. Describe active transport as a mechanism for the passage of drug through biological membranes.	**06**
	(b)	Explain USP dissolution apparatus III, IV and V with diagram.	**05**
	(c)	Discuss Matrixing and Bracketing Techniques.	**05**

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