Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Ph. - SEMESTER–VII • EXAMINATION – SUMMER-2017

Subject Code: 2270001 **Date: 27/04/2017**
Subject Name: DOSAGE FORM DESIGN-I
Time: 02:30 PM to 05:30 PM **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 preformulation? Discuss the significance of particle size and shape in formulation.	**06**
	(b)	How can preformulation be characterized? Suggest different means to arrest hydrolysis of APIs.	**05**
	(c)	Explain: 1) Overages 2) Climatic Zones	**05**
Q.2	**(a)**	Differentiate absolute and relative bioavailability. Discuss the pharmacokinetic methods for the bioavailability measurement.	**06**
	(b)	Discuss Matrixing and Bracketing Techniques: Purpose and objective.	**05**
	(c)	Discuss the regulatory requirements for conduction of bio-equivalence studies.	**05**
Q.3	**(a)**	Explain various methods used for enhancement of bioavailability.	**06**
	(b)	Explain: Volume of distribution. Discuss the kinetics of protein drug binding.	**05**
	(c)	Write a note on similarity factor and dissimilarity factor.	**05**
Q.4	**(a)**	Describe biowaiver based on BCS and dissolution.	**06**
	(b)	Describe the methods for comparison of dissolution profile.	**05**
	(c)	Explain renal clearance.	**05**
Q.5	**(a)**	Write a note on 'Biodegradable Polymers'.	**06**
	(b)	What do you understand by adjuvants? How are they utilized in designing innovative dosage forms?	**05**
	(c)	What is gastric emptying? Describe its role in drug absorption.	**05**
Q. 6	**(a)**	Enlist the various mechanism of transport of drug across biological barriers. Discuss any one mechanism in details.	**06**
	(b)	Enlist the cellulosic derivative polymers. Explain Hydroxy Propyl Methyl Cellulose.	**05**
	(c)	Discuss the factors affecting drug dissolution.	**05**
Q.7	**(a)**	Discuss stability testing of new drug substances and products as per ICH guideline.	**06**
	(b)	Classify the polymers. Discuss in brief about polymer properties.	**05**
	(c)	What in the meaning of prodrugs. Give its application in formulation.	**05**

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