Seat No.: Enr	olment No.
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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:

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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) (c)	Discuss Matrixing and Bracketing Techniques: Purpose and objective. Discuss the regulatory requirements for conduction of bio-equivalence studies.	05 05
Q.3	(a) (b) (c)	Explain various methods used for enhancement of bioavailability. Explain: Volume of distribution. Discuss the kinetics of protein drug binding. Write a note on similarity factor and dissimilarity factor.	06 05 05
Q.4	(a) (b) (c)	Describe biowaiver based on BCS and dissolution. Describe the methods for comparison of dissolution profile. Explain renal clearance.	06 05 05
Q.5	(a) (b)	Write a note on 'Biodegradable Polymers'. What do you understand by adjuvants? How are they utilized in designing innovative dosage forms?	06 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) (c)	Classify the polymers. Discuss in brief about polymer properties. What in the meaning of prodrugs. Give its application in formulation.	05 05
