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Date: 02-11-2017

Seat No.: Enrolment No.

GUJARAT TECHNOLOGICAL UNIVERSITY B.Pharm - SEMESTER-VII • EXAMINATION - WINTER-2017

Subject Name: Dosage Form Design-I

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

Instructions:

1. Attempt any five questions.

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- 2. Make suitable assumptions wherever necessary.
- 3. Figures to the right indicate full marks.

Q.1	(a)	Explain the influence of chemical properties of drugs on formulation and stability of the products.	06
	(b)	Discuss theoretical aspects for determining solubility and permeability of the drug and its assessment.	05
	(c)	Enlist additives used in tablet dosages form. Discuss the anti frictional agents.	05
Q.2	(a) (b)	Write a note on prodrugs. Effect of physical properties of drug like physical form, particle size and shape on formulation, stability and bioavailability.	06 05
	(c)	Write a note on Biodegradable polymers.	05
Q.3	(a) (b) (c)	Explain the role of biopharmaceutics in formulation development. Write a note on polymers used for achieving modified drug release. Explain various types of equivalence. How Latin square cross over design works?	06 05 05
Q.4	(a) (b)	Write a note on factors affecting drug absorption. Discuss the regulatory requirements for conduction of bio-equivalence studies.	06 05
	(c)	Volunteer selection for bioavailability studies is a critical issue. Discuss the statement with examples.	05
Q.5	(a) (b) (c)	Enumerate the drug transport mechanisms. Discuss passive diffusion in detail. What is BCS classification? How does it affect development of dosage form? How temperature degradation study is applied to pharmaceutical formulations? Derive an equation for half-life and method to establish expiry date and overages in formulations.	06 05 05
Q. 6	(a) (b) (c)	Write in detail about facilitated diffusion and pinocytosis. Explain USP dissolution apparatus III, IV and V with diagram. Discuss the factors affecting stability of pharmaceutical formulation.	06 05 05
Q.7	(a)	What is the importance of protein binding of drugs? Describe tissue binding of drugs in detail.	06
	(b) (c)	Storage conditions for stability testing as per ICH guidelines. What is matrixing and bracketing?	05 05
