Seat No.: _____ Enrolment No._____

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

Subject code: 270001 **Date: 02-11-2017**
Subject Name: Dosage Form Design- I
Time: 10:30 am to 01:30 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)	Define Preformulation. Enumerate outline of the principle areas of prefromulation research. Discuss in details about bulk characterization in preformulation.	**06**
	(b)	Discuss the significance of solubility and dissolution on formulation, stability and bioavailability of dosage form.	**05**
	(c)	Define polymorphism. Give their types. Discuss the importance of polymorphism in preformulation.	**05**
Q.2	(a)	Write a note on Improvement of stability and oral bioavailability using prodrugs.	**06**
	(b)	Explain following terms for preformulation drug characterization: Hydrolysis, Oxidation, Photolysis, pH, Excipient compatibility	**05**
	(c)	Discuss the methods to ascertain the order of a reaction.	**05**
Q.3	(a)	Give significance of any two with suitable examples: Antioxidants, preservatives, colouring agents, flavoring agents	**06**
	(b)	Enumerate excipients used in solid dosage form. Discuss diluents and binders in details.	**05**
	(c)	Write a short note on suspending agents and emulsifiers with examples.	**05**
Q.4	(a)	Write a short note on Accelerated Stability Studies.	**06**
	(b)	Discuss bracketing and matrixing designs for stability testing of drug substances and drug products as per ICH guidelines.	**05**
	(c)	Explain shelf life and overages? Describe calculation of overages.	**05**
Q.5	(a)	Enumerate the mechanisms of drug absorption. Discuss passive diffusion in detail.	**06**
	(b)	Enumerate factors affecting GI absorption of a drug from its dosage form.	**05**
	(c)	Enumerate Physiologic barriers to drug distribution in the body. Explain Blood – Brain barrier in detail.	**05**
Q. 6	(a)	Define Bioavailability. What are objectives of Bioavailability studies? Enumerate the factors affecting Bioavailability of a drug from its dosage form.	**06**
	(b)	Describe Type I dissolution apparatus with a labeled diagram.	**05**
	(c)	Discuss the factors affecting renal excretion of drugs.	**05**
Q. 7	(a)	Write a short note on pharmacokinetic methods to measures bioavailability.	**06**
	(b)	Enumerate factors influencing the drug dissolution that are related to physicochemical properties of drugs. Explain any two in details.	**05**
	(c)	Give equations of similarity factor (f_2) and dissimilarity factor (f_1) for Dissolution profile comparison.	**05**

****