

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 preformulation 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**
