

Seat No.: \_\_\_\_\_

Enrolment No. \_\_\_\_\_

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**B. Pharm. – SEMESTER – VII • EXAMINATION – SUMMER 2013**

**Subject Code: 270001**

**Date: 10-05-2013**

**Subject Name: Dosage Form Design-I**

**Time: 02.30 am - 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 prodrug approach is useful to increase the bioavailability of drug? **05**
- (c) What are physicochemical factors affecting preformulation study? **05**
- Discuss the importance of polymorphism in preformulation.
- Q.2** (a) Classify additives used in pharmaceutical formulations. **06**
- Describe in detail about suspending agents.
- (b) Discuss in detail antifrictional agent and disintegrating agent. **05**
- (c) Write a short note on ointment bases. **05**
- Q.3** (a) Discuss stability testing of new drug substances and products as per ICH guideline. **06**
- (b) What is matrixing and bracketing? **05**
- (c) Define: Formulation stability and MKT. Describe climate zone according to stability studies. **05**
- Q.4** (a) Enumerate the drug transport mechanisms. Discuss passive diffusion in detail. **06**
- (b) What is gastric emptying? Describe its role in drug absorption. **05**
- (c) Explain: Volume of distribution. Discuss the kinetics of protein drug binding. **05**
- Q.5** (a) Define absolute and relative bioavailability. Discuss plasma level time studies for measurement of bioavailability. **06**
- (b) Explain various types of equivalence. How Latin square cross over design works? **05**
- (c) What are the various levels of *in vitro-in vivo* correlation? **05**
- Q. 6** (a) Describe the methods for comparison of dissolution profile. **06**
- (b) What are the ideal features expected from dissolution apparatus? **05**
- (c) Discuss the significance of BCS system. **05**
- Q. 7** (a) Define clearance and renal clearance ratio of drug. Describe factors influencing renal excretion of drug. **06**
- (b) What are overages? Describe calculation of overages. **05**
- (c) Describe the importance of solubility in preformulation. **05**

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