

**GUJARAT TECHNOLOGICAL UNIVERSITY****B. Pharm. – SEMESTER – VII • EXAMINATION – SUMMER • 2015****Subject Code: 270001****Date: 11-05-2015****Subject Name: Dosage Form Design-I****Time: 02:30 pm - 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.**

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|------------|--|-----------|
| <b>Q.1</b> | (a) Define Preformulation? Explain the physicochemical properties related to solubility analysis in Preformulation.  | <b>06</b> |
|            | (b) What is BCS? Classify and give the significance of this system.  | <b>05</b> |
|            | (c) Storage conditions for stability testing as per ICH guidelines.  | <b>05</b> |
| <b>Q.2</b> | (a) Explain accelerated stability studies to find out shelf life with limitations as per ICH guidelines.   | <b>06</b> |
|            | (b) Discuss various factors affecting dissolution.   | <b>05</b> |
|            | (c) The role of polymorphism and crystallinity in Preformulation.  | <b>05</b> |
| <b>Q.3</b> | (a) (i) Describe Overages with methods of calculating it.  | <b>06</b> |
|            | (ii) Discuss about preservatives and anti-oxidants.  |           |
|            | (b) What are the physiologic barriers to distribution of drugs?  | <b>05</b> |
|            | (c) Discuss the absorption of drugs from non-oral extravascular routes.  | <b>05</b> |
| <b>Q.4</b> | (a) (i) World climatic zones as per ICH guidelines   | <b>06</b> |
|            | (ii) Bracketing and Matrixing  |           |
|            | (b) Describe active transport and passive diffusion mechanism for absorption.  | <b>05</b> |
|            | (c) Effect of salt formation and racemization in Preformulation.   | <b>05</b> |
| <b>Q.5</b> | (a) Differentiate absolute and relative bioavailability. Discuss the pharmacokinetic methods for the bioavailability measurement.  | <b>06</b> |
|            | (b) <i>In-vitro</i> - <i>In-vivo</i> correlations.   | <b>05</b> |
|            | (c) Explain USP dissolution apparatus III, IV and V with diagram.  | <b>05</b> |
| <b>Q.6</b> | (a) What are the physiologic properties of drug that affect the absorption of drug?  | <b>06</b> |
|            | (b) Discuss the factors affecting stability of drug.   | <b>05</b> |
|            | (c) Explain renal clearance.   | <b>05</b> |
| <b>Q.7</b> | (a) How the bioavailability of drug can be improved?   | <b>06</b> |
|            | (b) Define bioequivalence. How bioequivalence study can be performed by Latin Square Cross Over Design?  | <b>05</b> |
|            | (c) The decomposition of glucose in aqueous acid solution was found to follow a first order. The initial concentration was found to be 0.071 M. The concentration after a period of 12 hours was $5.2 \times 10^{-2}$ mole/liter. (i) Calculate reaction rate constant (ii) Estimate the amount of glucose lost during the period of 24 hours. | <b>05</b> |