

GUJARAT TECHNOLOGICAL UNIVERSITY
BPHARM – SEMESTER VII • EXAMINATION – WINTER • 2016

Subject code: 2270001**Date: 17-11-2016****Subject Name: Dosage Form Design - I****Time: 10:30 am - 01:30 pm****Total Marks: 70****Instructions:**

1. Attempt all questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

Q-1

- a. Define Half life, Self life and Overage. Discuss about international climatic zones as per ICH guideline **06**
- b. Discuss Matrixing and Bracketing Techniques: Purpose and objective. **05**
- c. Explain accelerated stability studies to find out shelf life with limitations as per ICH guidelines. **05**

Q-2

- a. Define preformulation. Write a note on physicochemical properties related to solubility study in preformulation. **06**
- b. Explain the role of polymorphism and crystallinity in Preformulation. Enlist the methods to identify polymorphism. **05**
- c. What do you understand by prodrug? Give its applications for improving stability of drug. **05**

Q-3

- a. Enlist various mechanisms of drug transport. Discuss active transport in detail. **06**
- b. Explain effect of pKa and pH on absorption parameter. **05**
- c. Short note on kinetics of Plasma protein binding. **05**

Q-4

- a. Write full name BCS with its classification. Give its objective. Write factors affecting drug dissolution with respect to test apparatus. **06**
- b. How the bioavailability of drug can be improved? **05**
- c. Write a note on similarity factor and dissimilarity factor. **05**

Q-5

- a. Define bioavailability and bioequivalence. Enlist methods of measurement of bioavailability. Discuss latin-square cross-over design. **06**
- b. Enlist the chemical properties observed during preformulation study. Explain oxidation in detail **05**
- c. Discuss criteria for waiver of in vivo bioavailability study with reference to drug product. **05**

Q-6

- a. Write a note on pharmaceutical excipients used as tablet binder and granulating agent. **06**
- b. Write a note on suspending agents and emulsifiers used in liquid formulations. **05**
- c. What do you understand by adjuvants? How are they utilized in designing innovative dosage forms? **05**

Q-7

- a. Discuss the effect of containers and closures on stability of pharmaceuticals. **06**
- b. Enlist the theories of dissolution. Explain in detail Film Theory **05**
- c. Volunteer selection for bioavailability studies is a critical issue. Discuss the statement with examples. **05**