

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**B.Ph. - SEMESTER-7 • EXAMINATION – WINTER -2023**

**Subject Code:2270001****Date:01/12/2023****Subject Name: Dosage form Design-I****Time: 10:30am to 01:30pm****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? Explain the physicochemical properties related to solubility analysis in Preformulation. **06**
- (b) Enumerate the chemical properties affecting preformulation studies in designing a dosage form and discuss any one in details giving suitable illustrations. **05**
- (c) What is the meaning of prodrugs. Give its application in formulation. **05**
- Q.2 (a) Describe the ideal properties of a preservative. **06**
- (b) Define biodegradable polymers? Explain its mechanism of biodegradation with suitable example **05**
- (c) Enlist the cellulosic derivative polymers. Give detail about Hypromellose. **05**
- Q.3 (a) Write a short note on matrixing and bracketing study design **06**
- (b) Define Half life, Self life and Overage. Discuss about international climatic zones as per ICH guideline. **05**
- (c) Describe Overages with methods of calculating it. **05**
- Q.4 (a) Enlist factors affecting gastro intestinal absorption. Discuss in detail effect of gastric emptying time on drug absorption. **06**
- (b) What are the physiologic barriers to distribution of drugs? **05**
- (c) Discuss the absorption of drugs from non-oral extravascular routes. **05**
- Q.5 (a) Explain bioavailability. Discuss its objective. Explain plasma level time studies for measurement of bioavailability. **06**
- (b) Define bioequivalence. Write a note on Latin square cross over design. **05**
- (c) How the bioavailability of drug can be improved? **05**
- Q.6 (a) Enlist the theories of dissolution. Explain in detail Noyes Whitney's Theory **06**
- (b) Describe *In-vitro* - *In-vivo* correlations. **05**
- (c) Explain Accelerated stability study and explain method for calculation of Shelf life. **05**
- Q.7 (a) Explain BCS. Give its objective. Write factors affecting drug dissolution with respect to test apparatus. **06**
- (b) Enlist the dissolution apparatus. Discuss Apparatus III, IV and V with labeled diagram. **05**
- (c) Define Dissolution profile. Write a note on similarity factor and dissimilarity factor. **05**