

GUJARAT TECHNOLOGICAL UNIVERSITY
B. Pharm. - SEMESTER-VII • EXAMINATION – SUMMER -2025

Subject Code: 2270001**Date: 15/05/2025****Subject Name: Dosage form Design I****Time: 02:30pm to 05:30pm****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) Explain preformulation studies. What is partition coefficient? What is its significance in preformulation? **06**
- (b) Write a note on Prodrug. Discuss Prodrug approaches. **05**
- (c) Write a note on polymorphism aspect of an API in relation to preformulation study. **05**
- Q.2** (a) Discuss physiological barriers to drug distribution in body. **06**
- (b) Enumerate the drug transport mechanisms. Discuss passive diffusion in detail. **05**
- (c) Explain plasma protein binding in detail. **05**
- Q.3** (a) What is the importance of an adjuvant in pharmaceutical products? Enlist cellulose derivatives polymers and write a note on HPMC. **06**
- (b) Classify additives used in pharmaceutical formulations. Describe in detail about suspending agents. **05**
- (c) Write a note on Biodegradable polymers. **05**
- Q.4** (a) Enumerate different factors affecting the stability of a dosage form and discuss each in brief. **06**
- (b) Define overages and discuss methods to determine overages. **05**
- (c) Explain accelerated stability study as per ICH guidelines. **05**
- Q.5** (a) Discuss remedies to overcome degradation due to hydrolysis and oxidation in pharmaceutical dosage form. **06**
- (b) Classify the methods for bioavailability measurement. Discuss the method based on plasma data. **05**
- (c) Enlist the theories of dissolution. Explain in detail Film Theory **05**
- Q.6** (a) What are similarity factor and dissimilarity factor, how are they calculated and give their significance. **06**
- (b) Define absolute and relative bioavailability. Describe Latin Square cross over design for bioequivalence study. **05**
- (c) Discuss the regulatory requirements for conduction of bioequivalence studies. **05**
- Q.7** (a) What is biorelevant dissolution media? Name the USP dissolution apparatus with the use. **06**
- (b) What is BCS? Classify and give the significance of this system **05**
- (c) Discuss in detail volume of distribution. **05**
