

GUJARAT TECHNOLOGICAL UNIVERSITY
B.Ph. - SEMESTER-VII • EXAMINATION – WINTER -2021

Subject Code:2270001**Date: 24/11/2021****Subject Name: Dosage Form Design I****Time: 10:30 AM TO 01:30 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) Discuss pH –Partition hypothesis briefly with suitable examples. Enumerate the assumptions of this hypothesis. **06**
- (b) Explain the role of polymorphism and crystallinity in preformulation. Enlist the methods to identify polymorphism. **05**
- (c) Discuss theoretical aspects for determining solubility and permeability of the drug and its assessment. **05**
- Q.2** (a) Enumerate the drug degradation pathways and discuss Hydrolysis in detail. **06**
- (b) Write a note on semi-synthetic cellulosic derivatives as pharmaceutical excipients. **05**
- (c) Define bioequivalence. Write a short note on Latin-square cross-over design. **05**
- Q.3** (a) Discuss the physiological factors influencing the drug absorption. **06**
- (b) Describe the influence of BBB and CSF barriers on distribution of drugs. **05**
- (c) Write in detail about facilitated diffusion. **05**
- Q.4** (a) Discuss the factors affecting stability of pharmaceutical formulation. **06**
- (b) Explain accelerated stability study as per ICH guidelines. **05**
- (c) Discuss the effect of containers and closures on stability of pharmaceuticals. **05**
- Q.5** (a) What are similarity factor and dissimilarity factor, how are they calculated and give their significance. **06**
- (b) Enlist various methods for measurement of bioavailability. Discuss any one in detail. **05**
- (c) Discuss the regulatory requirements for conduction of bio-equivalence studies. **05**
- Q. 6** (a) Explain USP dissolution apparatus III, IV and V with diagram. **06**
- (b) Write a note on Biodegradable polymers. **05**
- (c) Discuss in detail volume of distribution. **05**
- Q.7** (a) What is BCS classification? How does it affect development of dosage form? **06**
- (b) What is the importance of protein binding of drugs? Describe tissue binding of drugs in detail. **05**
- (c) Write a note on drug clearance. **05**
