

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
B.PHARM - SEMESTER- 7 EXAMINATION – SUMMER -2019

Subject Code: 270001**Date: 06-05-2019****Subject Name: Dosage Form Design- I****Time: 02:30 PM TO 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.

- Q.1** (a) Discuss the significance of solubility and dissolution on formulation, stability and bioavailability of dosage form. **06**
- (b) Explain the physicochemical properties of drug substance that affect the absorption of drug. **05**
- (c) What is therapeutic equivalence? Enlist various *in-vivo* and *in-vitro* approaches that can be utilized to establish bioequivalence. **05**
- Q.2** (a) Write a note on Polymorphism giving examples. **06**
- (b) Write a note on Improvement of stability and oral bioavailability using prodrugs. **05**
- (c) What is BCS? Classify and give the significance of this system. **05**
- Q.3** (a) Discuss different approaches for prevention of chemical degradation of pharmaceuticals. **06**
- (b) Storage conditions for stability testing as per ICH guidelines. **05**
- (c) Describe active transport and passive diffusion mechanism for absorption. **05**
- Q.4** (a) Explain USP dissolution apparatus III, IV and V with diagram. **06**
- (b) Write a note on suspending agents and emulsifiers used in liquid formulations. **05**
- (c) Explain kinetic involved in protein drug binding with description of plots. **05**
- Q.5** (a) Discuss bracketing and matrixing designs for stability testing of drug substances and drug products as per ICH guidelines. **06**
- (b) Explain renal clearance. **05**
- (c) Explain photodegradation and its prevention. **05**
- Q.6** (a) What are the objectives of bioavailability study? Explain measurement of bioavailability by Plasma level-time study. **06**
- (b) Define Intrinsic dissolution rate. Discuss factors affecting rate of dissolution. **05**
- (c) Write a brief note on overages. **05**
- Q.7** (a) Enumerate factors affecting GI absorption of drugs. Explain theory of dissolution. **06**
- (b) Write a note on disintegrating agents. **05**
- (c) Write a note on Drug Interactions. **05**