

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
B. Pharm. – SEMESTER – VII • EXAMINATION – SUMMER • 2014

Subject Code: 270001

Date: 03-06-2014

Subject Name: Dosage Form Design-I

Time: 10:30 am – 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) Define polymorphism and pseudo-polymorphism. Enlist the methods to identify polymorphism. Comment on dissolution behavior and stability of polymorphs. **06**
- (b) What is Preformulation? How can it be characterized? Suggest different means to arrest hydrolysis of APIs. **05**
- (c) How is the particle engineering influence the development of compacted APIs and its compressed dosage form? **05**
- Q.2** (a) Enlist additives used in tablet dosages form. Discuss the anti frictional agents. **06**
- (b) Explain term emulsifiers & suspending agent w.r.t. pharmaceutical formulation. Give the classification of emulsifying agents. **05**
- (c) Discuss the role of binders in compressed pharmaceutical dosages form. **05**
- Q.3** (a) Define bioavailability and bioequivalence. Enlist methods of measurement of bioavailability. Discuss latin-square cross-over design. **06**
- (b) Give regulatory requirements for conduction of bio-equivalent studies. **05**
- (c) What is Gastric emptying? Explain influence of food on drug absorption. **05**
- Q.4** (a) Enlist various barriers to drug absorption. Describe passive diffusion of drug. **06**
- (b) What is biopharmaceutics? Explain its role in formulation development. **05**
- (c) Discuss the physiological factor influencing drug absorption. **05**
- Q.5** (a) Discuss the requirement related to stability testing with emphasizing matrixing/ bracketing technique and climatic zones. **06**
- (b) How is accelerated stability study carried out? How the results of it can be correlated with real time study? **05**
- (c) Define kinetics. Discuss the order of reaction with respect of stability testing. **05**
- Q. 6** (a) What is BCS? Give its objectives & classification. Give condition for justifying request of biowaiver. **06**
- (b) Enumerates factors affecting dissolution of drug, discuss factors related to drug product formulation. **05**
- (c) Give the significance of dissolution profile comparison. Explain similarity factor for dissolution comparison. **05**
- Q. 7** (a) What are overages? Give its permitted limit. Describe its calculations. **06**
- (b) Write note on Plasma protein binding **05**
- (c) Discuss the factors affecting on drug formulation stability **05**
