

GUJARAT TECHNOLOGICAL UNIVERSITY
B.Pharm - SEMESTER-VII • EXAMINATION – SUMMER -2021

Subject Code: 2270001**Date:03/08/2021****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) What is the importance of preformulation study? Discuss oxidation reaction in detail and different means to arrest it as a part of preformulation study. **06**
- (b) Write a note on prodrug approach. **05**
- (c) What do you mean by drug-excipient compatibility study? Which are the different methods to determine it? **05**
- Q.2** (a) What is the importance of an adjuvant in pharmaceutical products? Enlist cellulose derivatives polymers and write a note on HPMC. **06**
- (b) Write a note on biodegradable polymers, **05**
- (c) Which different categories of excipients are utilized in a tablet dosage form? Discuss any one in detail. **05**
- Q.3** (a) How can one maintain the shelf life by means of overages? What is its limit of addition? Discuss in detail method to calculate overages. **06**
- (b) What do you mean by order of reaction? Which are the different methods to determine order of reaction? **05**
- (c) What do you mean by reduced and full design in stability testing? Write a note on matrixing design. **05**
- Q.4** (a) Compare and contrast passive and facilitated diffusion process. **06**
- (b) Explain plasma protein binding in detail. **05**
- (c) Discuss physiological barriers to drug distribution in body. **05**
- Q.5** (a) Define bioavailability. Discuss methods to enhance the bioavailability. **06**
- (b) Discuss the merits and demerits of using healthy volunteers and patients for bioavailability study. **05**
- (c) Draw a layout of latin square crossover design for 12 subjects to compare three different formulations A, B and C. Discuss the advantages and limitations of this design. **05**
- Q. 6** (a) Enlist factors affecting dissolution. Discuss factors related to drug product formulation in detail. **06**
- (b) Give full form of BDDCS. What is its importance and applications in drug discovery and development? **05**
- (c) Classify methods for dissolution profile comparison and discuss model independent method in brief. **05**
- Q.7** (a) Enumerate theories of dissolution. Explain in brief 'Film Theory' **06**
- (b) What are the various non-renal routes of drug excretion? **05**
- (c) Discuss the regulatory requirements for conduction of bio-equivalence studies **05**