

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**B.PHARM - SEMESTER- 7 EXAMINATION – SUMMER -2023**

**Subject Code: 2270001****Date: 30/06/2023****Subject Name: Dosage form Design I****Time:02.30 p.m. to 5.30 p.m.****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) How is the preformulation study of IR tablet dosage form of an API belonging to BCS Class II is carried out? **06**
- (b) Summarize applications of free-flowing powders in pharmacy and discuss methods for their characterization. **05**
- (c) Write a note on polymorphism aspect of an API in relation to preformulation study **05**
- Q.2** (a) Explain the role of polymers in pharmaceutical drug delivery. **06**
- (b) Which different categories of pharmaceutical adjuvants are used as disintegrants? Discuss any one of them in detail. **05**
- (c) Write a short note on natural gums used as pharmaceutical necessities. **05**
- Q.3** (a) Define: (a) Reaction rate. (b) Overages. (c) Half-life **06**
- (b) How is an order of reaction determined? Discuss different approaches utilized to determine it. **05**
- (c) Enumerate different factors affecting the stability of a dosage form and discuss each in brief. **05**
- Q.4** (a) Differentiate between Active transport and Passive transport process for drug absorption. **06**
- (b) Draw a schematic diagram depicting absorption of drugs from orally administered solid dosage form and explain the steps involved in it. **05**
- (c) Which are the different theories of drug dissolution? Write in detail regarding Film theory of dissolution. **05**
- Q.5** (a) Define the following — Therapeutic equivalence, Pharmaceutical equivalence and Bioequivalence. **06**
- (b) Enlist the elements of a bioequivalence study protocol. **05**
- (c) Give an overview of various excretory routes, mechanism of drug transport and nature of drug excreted involved in drug excretion process. **05**
- Q. 6** (a) Tabulate different types of compendial dissolution apparatus according to USP and their applications and discuss dissolution methodology used for IR drug product based on BCS **06**
- (b) What is the importance of similarity factor  $f_2$  in dissolution profile comparison? **05**
- (c) Write a short note on BDDCS. **05**
- Q.7** (a) Enlist different approaches for increasing and decreasing the solubility of drug. Discuss any one from each in detail. **06**
- (b) Define apparent volume of distribution. Why cannot the volume of distribution of a drug have a true physiologic meaning? **05**
- (c) Why protein binding of drugs is important to study in field of biopharmaceutics? **05**