

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B. Pharm-Semester-VII May-2012 Examination

Subject code: 270001

Subject Name: Dosage Form Design- I

Time: 02:30pm to 5:30pm

Date: 23-05-2012

Instructions:

Total Marks: 80

1. Attempt any five questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

- Q.1** (a) **Comment on the following** **08**
1. Drug-excipients interaction can be minimized by preformulation studies
 2. Passive transport is inhibited by metabolic poison
 3. Maintenance of sink condition is important in *in-vitro* dissolution for poorly soluble drugs
 4. Change in urinary pH alters the bioavailability of weakly acidic/basic drugs
- (b) Discuss the factors affecting selection of organoleptic additives **05**
- (c) Give the equation and significance of similarity and dissimilarity factor **03**
- Q.2** (a) Enumerate the compendial apparatus for dissolution studies. Discuss in detail any two **05**
- (b) Write a note on “Accelerated stability studies” **06**
- (c) Bioavailability of drug is studied in 12 volunteers. The average AUC (0-48 h) and the dose administered are given in the table **05**
- | Drug product | Dose (mg) | AUC (mcg/ml-h) |
|---------------|-----------|----------------|
| Oral tablet | 200 | 79.5 |
| Oral solution | 200 | 86.1 |
| IV bolus | 50 | 37.8 |
- Calculate:
1. The relative bioavailability of Tablet compared to oral solution
 2. Absolute bioavailability of the drug from the solutions
- Q.3** (a) Significance of protein binding **06**
- (b) Write a note on “Blood brain barrier” **05**
- (c) Write a note on “Antioxidants” **05**
- Q.4** (a) Discuss in detail - ICH guidelines for stability testing of various dosage forms **07**
- (b) Explain in detail Polymorphism and Amorphism **07**
- (c) What do you mean by Total body clearance **02**
- Q.5** (a) Explain- Glomerular filtration **05**
- (b) Write short note on – IVIVC **06**
- (c) Explain carrier mediated absorption **05**

- Q. 6** (a) Enlist the Patient related factors affecting drug absorption. Discuss any one **06**
(b) BCS classification and its significance **05**
(c) pKa of weakly acidic drug is 5.5. If pH of patient urine is 6.5, what will be the ratio of ionized to unionized drug. **05**
- Q.7** (a) **Explain in brief** **12**
1. Bioavailability and bioequivalence
2. Pharmacokinetics and clinical pharmacokinetics
3. Intrinsic solubility and dissolution rate
4. Absolute surface area and effective surface area
(b) Discuss soft drugs and pro drugs with examples **04**
