

Seat No.: _____

Enrolment No. _____

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

Subject Code: 270001

Date: 25-11-2014

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) 1) Preformulation studies are initiated after API is approved. Comment. | 02 |
| | 2) Crystal habit and internal structure of drug can affect the physicochemical properties. Comment. | 02 |
| | 3) Give an example how polymorphism can affect drug bioavailability. | 02 |
| | (b) What are the problems faced in formulation of BCS Class II drugs? Discuss suitable strategies to overcome them. | 05 |
| | (c) Enumerate bulk characterization parameters. Explain any one in detail | 05 |
| Q.2 | (a) What are prodrugs? Enlist the advantages of prodrugs giving examples. | 06 |
| | (b) Write a note on disintegrating agents. | 05 |
| | (c) Explain the factors affecting renal excretion. | 05 |
| Q.3 | (a) 1) The addition of antifrictional agents always enhances the flow properties. Comment. | 02 |
| | 2) A drug is easily hydrolysable. Suggest suitable remedies for its formulation. | 02 |
| | 3) Define oxidation. How do antioxidants prevent oxidation? | 02 |
| | (b) What are preservatives? Why are they required in pharmaceutical formulations? Give four examples. | 05 |
| | (c) Write a note on similarity factor and dissimilarity factor. | 05 |
| Q.4 | (a) Explain: 1) Shelf life 2) Overages 3) Climatic Zones | 06 |
| | (b) What are ICH guidelines? Write a note on ICH guidelines for stability studies. | 05 |
| | (c) Write a note on stability studies for liquid oral products. | 05 |
| Q.5 | (a) Enumerate factors affecting GI absorption of drugs. Explain theory of dissolution. | 06 |
| | (b) Describe the importance of volume of distribution in detail. | 05 |
| | (c) What is the importance of protein binding of drugs? Describe tissue binding of drugs in detail. | 05 |
| Q. 6 | (a) Discuss various methods used for the measurement of bioavailability. | 08 |
| | (b) Volunteer selection for bioavailability studies is a critical issue. Discuss the statement with examples. | 05 |
| | (c) Briefly describe the interpretation of results of bioequivalence studies. | 03 |

- Q. 7**

(a)

What is randomization? Write a note on Latin Square Crossover Design.

06

(b)

Explain dissolution test apparatus with a neat sketch.

05

(c)

Following data is obtained for 4 formulations of aminophylline in volunteers of average 50 kg weight:
What is the absolute bioavailability of the drug from capsule? What is the relative bioavailability of the SR tablet against oral solution?

05

Drug product	Dose (mg/kg)	AUC(mcg.hr/l)
i.v. solution	1.2	450
Oral solution	4.0	822
Oral capsule	4.0	736
Oral S R tablet	8.0	1040
