

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.**

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|-------------|-----|---|-----------|
| 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: **05**

What is the absolute bioavailability of the drug from capsule? What is the relative bioavailability of the SR tablet against oral solution?

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
