

GUJARAT TECHNOLOGICAL UNIVERSITY
B.PHARM- SEMESTER-VII • EXAMINATION – WINTER-2016

Subject Code: 270001**Date: 17/11/2016****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) | Define polymorphism. Explain its importance in preformulation study with example. | 06 |
| | (b) | Write a brief note on overages. | 05 |
| | (c) | Describe the Accelerated stability study with its limitation. | 05 |
| Q.2 | (a) | Discuss Pharmaceutical application of Prodrug. | 06 |
| | (b) | Discuss the role of diluents in solid dosage form. | 05 |
| | (c) | Write a note on Preservatives. | 05 |
| Q.3 | (a) | Explain the physicochemical properties of drug substance that affect the absorption of drug. | 06 |
| | (b) | Write a note on volume of distribution. | 05 |
| | (c) | Discuss the Photolysis reaction in detail. | 05 |
| Q.4 | (a) | Discuss the factor affecting renal clearance. | 06 |
| | (b) | Describe USP Type-II dissolution apparatus. | 05 |
| | (c) | Write a note on BCS classification system. | 05 |
| Q.5 | (a) | Discuss the effect of container and closures on stability of Pharmaceutical dosage form. | 06 |
| | (b) | Explain Latin square cross over design in Bioequivalence study. | 05 |
| | (c) | Discuss the criteria for waivers of in vivo Bioequivalence studies. | 05 |
| Q. 6 | (a) | Write a note on Bracketing & matrixing design in stability study. | 06 |
| | (b) | Write a note on disintegrating agents. | 05 |
| | (c) | Discuss the role of solubility in Preformulation study. | 05 |
| Q.7 | (a) | Write a note on Plasma Protein Drug Binding. | 06 |
| | (b) | Write a note on similarity factor and difference factor in dissolution profile comparison. | 05 |
| | (c) | Discuss Drug-Excipients compatibility study in detail | 05 |
