Seat No.: _____ Enrolment No. _____

# 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** |

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