Seat No.: _____ Enrolment No. _____

# GUJARAT TECHNOLOGICAL UNIVERSITY

**B.Pharm- SEMESTER–VII • EXAMINATION – WINTER -2020**

**Subject Code: 2270001** **Date:01/01/2021**

**Subject Name: Dosage Form Design-I**

**Time: 10:30AM To 12:30PM** **Total Marks: 54**

**Instructions:**

1. **Attempt any THREE questions from Q-1 to Q-6.**
2. **Q.7 is compulsory to attempt.**
3. **Make suitable assumptions wherever necessary.**
4. **Figures to the right indicate full marks.**

| | | | |
|---|---|---|---|
| **Q.1** | **(a)** | What is Preformulation? Discuss the significance of particle size and shape in formulation. | **06** |
| | **(b)** | Explain the role of polymorphism and crystallinity in Preformulation. Enlist the methods to identify polymorphism. | **05** |
| | **(c)** | Enlist the chemical properties observed during preformulation study. Explain oxidation and reduction in detail. | **05** |
| **Q.2** | **(a)** | Classify the polymers. Discuss in brief about polymer properties. | **06** |
| | **(b)** | Write a short note on “Plasma Protein Binding”. | **05** |
| | **(c)** | Write a short note on Natural Gums. | **05** |
| **Q.3** | **(a)** | Explain various methods used for enhancement of bioavailability. | **06** |
| | **(b)** | Explain the role of Biopharmaceutics in formulation development. | **05** |
| | **(c)** | Discuss the regulatory requirements for conduction of bio-equivalence Studies. | **05** |
| **Q.4** | **(a)** | Write a note on factors affecting drug absorption. | **06** |
| | **(b)** | Define i) Bioavailability ii) Cmax iii) tmax iv) Overage v) Mean Kinetic Temperature | **05** |
| | **(c)** | What is IVIVC? Describe In-vitro -In-vivo correlations levels. | **05** |
| **Q.5** | **(a)** | What is BCS classification? How does it affect development of dosage form? | **06** |
| | **(b)** | Discuss Matrixing and Bracketing Techniques. | **05** |
| | **(c)** | Effect of pKa and pH on absorption parameter. | **05** |
| **Q. 6** | **(a)** | Define Half-life and Self life. Discus about international climatic zones as per ICH guideline | **06** |
| | **(b)** | Discuss the factors affecting stability of pharmaceutical formulation. | **05** |
| | **(c)** | Discuss the effect of containers and closures on stability of pharmaceuticals. | **05** |
| **Q.7** | **(a)** | Discuss stability testing of new drug substances and products as per ICH guideline. | **06** |
| | | **OR** | |
| | **(a)** | Write a note on volume of distribution. | **06** |
| | | **OR** | |
| | **(a)** | Storage conditions for stability testing as per ICH guidelines. | **06** |

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