

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.

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|-------------|--|-----------|
| 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 |
