

GUJARAT TECHNOLOGICAL UNIVERSITY
B.PHARM - SEMESTER- 7 EXAMINATION – SUMMER -2019

Subject Code: 270001

Date: 06-05-2019

Subject Name: Dosage Form Design- I

Time: 02:30 PM TO 05:30 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) | Discuss the significance of solubility and dissolution on formulation, stability and bioavailability of dosage form. | 06 |
| | (b) | Explain the physicochemical properties of drug substance that affect the absorption of drug. | 05 |
| | (c) | What is therapeutic equivalence? Enlist various <i>in-vivo</i> and <i>in-vitro</i> approaches that can be utilized to establish bioequivalence. | 05 |
| Q.2 | (a) | Write a note on Polymorphism giving examples. | 06 |
| | (b) | Write a note on Improvement of stability and oral bioavailability using prodrugs. | 05 |
| | (c) | What is BCS? Classify and give the significance of this system. | 05 |
| Q.3 | (a) | Discuss different approaches for prevention of chemical degradation of pharmaceuticals. | 06 |
| | (b) | Storage conditions for stability testing as per ICH guidelines. | 05 |
| | (c) | Describe active transport and passive diffusion mechanism for absorption. | 05 |
| Q.4 | (a) | Explain USP dissolution apparatus III, IV and V with diagram. | 06 |
| | (b) | Write a note on suspending agents and emulsifiers used in liquid formulations. | 05 |
| | (c) | Explain kinetic involved in protein drug binding with description of plots. | 05 |
| Q.5 | (a) | Discuss bracketing and matrixing designs for stability testing of drug substances and drug products as per ICH guidelines. | 06 |
| | (b) | Explain renal clearance. | 05 |
| | (c) | Explain photodegradation and its prevention. | 05 |
| Q. 6 | (a) | What are the objectives of bioavailability study? Explain measurement of bioavailability by Plasma level-time study. | 06 |
| | (b) | Define Intrinsic dissolution rate. Discuss factors affecting rate of dissolution. | 05 |
| | (c) | Write a brief note on overages. | 05 |
| Q.7 | (a) | Enumerate factors affecting GI absorption of drugs. Explain theory of dissolution. | 06 |
| | (b) | Write a note on disintegrating agents. | 05 |
| | (c) | Write a note on Drug Interactions. | 05 |