

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
B.PHARM – SEMESTER – 7- EXAMINATION –WINTER - 2018

Subject Code: 2270001

Date: 15/11/2018

Subject Name: Dosage form Design I

Time: 10:30 AM TO 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 Preformulation studies. Explain steps involved in Preformulation studies. | 06 |
| | (b) How polymorphism and crystallinity influence performance of drug product. Explain in brief methods to identify polymorphism and crystallinity. | 05 |
| | (c) Define diluents. Classify Diluents. Write a note on versatility of lactose as diluents in oral solid dosage forms. | 05 |
| Q.2 | (a) Define disintegrating agent. Give examples of commonly used disintegrating agents. Write mechanism of disintegration. | 06 |
| | (b) What do you mean by polymer? Write a note on polymers used in different dosage forms with examples. | 05 |
| | (c) Write short note on passive diffusion. | 05 |
| Q.3 | (a) Write a note on Prodrug. Discuss Prodrug approaches. | 06 |
| | (b) Write a short note on Matrixing and Bracketing study design. | 05 |
| | (c) Define bioequivalence. Write a short note on Latin-square cross-over design. | 05 |
| Q.4 | (a) Write a note on factors affecting on stability of pharmaceutical dosage form. | 06 |
| | (b) Discuss in detail volume of distribution. | 05 |
| | (c) How purity of API and drug degradation are studied in product development? | 05 |
| Q.5 | (a) Discuss Noyes Whitney equation for rate of dissolution. Discuss USP type I apparatus for dissolution. | 06 |
| | (b) Define overages and discuss methods to determine overages. | 05 |
| | (c) Discuss remedies to overcome degradation due to hydrolysis and oxidation in pharmaceutical dosage form. | 05 |
| Q. 6 | (a) Define biopharmaceutics. Enlist various mechanisms of drug transport. Discuss active transport in detail. | 06 |
| | (b) Draw a well labelled diagram of cell membrane and Discuss Endocytosis. | 05 |
| | (c) Define relative and absolute bioavailability. Discuss plasma level time studies for measurement of bioavailability. | 05 |
| Q.7 | (a) Write a short note on “Plasma Protein Binding” | 06 |
| | (b) Discuss tissue permeability of drug in distribution. | 05 |
| | (c) Write a note on drug clearance. | 05 |
