

GUJARAT TECHNOLOGICAL UNIVERSITY
B.PHARM - SEMESTER- 7 EXAMINATION – SUMMER -2020

Subject Code: 2270001**Date:26-10-2020****Subject Name: Dosage form Design I****Time: 2:30 PM TO 5:30 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 Pre-Formulation study. Enlist techniques used in it. Describe any one of them to ascertain Drug-Excipient Compatibility. | 06 |
| | (b) Explain the influence of chemical properties of drugs on formulation and stability of the products. | 05 |
| | (c) Explain: 1) Overages 2) Climatic Zones. | 05 |
| Q.2 | (a) Discuss Effect of physical properties of drug like physical form, particle size and shape on formulation, stability and bioavailability. | 06 |
| | (b) Enlist additives used in tablet dosages form. Discuss the anti frictional agents. | 05 |
| | (c) Write a note on prodrugs. | 05 |
| Q.3 | (a) Classify additives used in pharmaceutical formulations. Describe in detail about suspending agents. | 06 |
| | (b) Discuss stability testing of new drug substances and products as per ICH Guideline. | 05 |
| | (c) Explain the characteristics of Active transport process. Write their application in the development of formulation and administration of drugs. | 05 |
| Q.4 | (a) Discuss the factors affecting stability of pharmaceutical formulation. | 06 |
| | (b) Describe Matrixing and bracketing in stability study. | 05 |
| | (c) What is IVIVC? Describe In-vitro - In-vivo correlations levels. | 05 |
| Q.5 | (a) Enumerate the factors affecting drug absorption from GIT. Discuss the effect of gastric emptying, drug pKa and GI pH on drug absorption. | 06 |
| | (b) Discuss plasma protein drug binding. | 05 |
| | (c) Enumerate the drug transport mechanisms. Discuss passive diffusion in detail. | 05 |
| Q.6 | (a) Write a note on similarity factor and dissimilarity factor. | 06 |
| | (b) Classify the methods for bioavailability measurement. Discuss the method based on plasma data. | 05 |
| | (c) Define absolute and relative bioavailability. Describe Latin Square cross over design for bioequivalence study. | 05 |
| Q.7 | (a) What is BCS? Classify and give the significance of this system | 06 |
| | (b) Discuss the factors affecting drug dissolution. | 05 |
| | (c) Explain USP dissolution apparatus III, IV and V with diagram. | 05 |