

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
M. Pharm. – SEMESTER – I • EXAMINATION – SUMMER 2013

Subject Code: 910102

Date: 15-05-2013

**Subject Name: Pharmaceutical Formulation,
Development and Biopharmaceutics**

Time: 10.30 am - 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) IVIVC can be improved by making necessary changes in the dissolution media, <i>in-vitro</i> dissolution set up and in the dosage form. Comment and discuss. | 06 |
| | (b) Discuss the pharmaceutical factors affecting preformulation. | 05 |
| | (c) Explain: Total Clearance, Volume of distribution. | 05 |
| Q.2 | (a) What are OVIs. What are their sources. Discuss its classification based on risk assessment of residual solvent. | 06 |
| | (b) Describe the ICH guidelines for Photostability testing of new drug substance and product. | 05 |
| | (c) Write a note on Protein Binding. | 05 |
| Q.3 | (a) Describe the dissolution apparatus for buccal tablets and transdermal patches. | 06 |
| | (b) Elaborate the necessity of drug-excipient compatibility study with examples. Discuss how it is carried out. | 05 |
| | (c) Give the importance of BCS in dosage form development. | 05 |
| Q.4 | (a) Give the details of diffusion layer model with respect to theories of dissolution. | 06 |
| | (b) Write a note on Biorelevant Media. | 05 |
| | (c) Describe the stability aspects of the biotechnologically derived products. | 05 |
| Q.5 | (a) Explain the meaning of the following terms related to stability: Accelerated stability testing, Long term stability testing, Forced degradation stability testing. | 06 |
| | (b) How crystallinity and polymorphism influences the dissolution of drug from the dosage form. | 05 |
| | (c) What are the objectives of IVIVC. Describe various levels of IVIVC correlation. | 05 |
| Q. 6 | (a) Enlist all techniques of dissolution enhancement and discuss any one in detail. | 06 |
| | (b) What are CACO2 cell lines. What are the merits, limitations and application of this cell lines. | 05 |
| | (c) Enlist the physiological factor affecting drug absorption. Describe any two. | 05 |
| Q.7 | (a) Discuss formulation and evaluation aspects of different types of shampoos. | 06 |
| | (b) What is importance of measuring plasma drug concentration. Describe different types of Pharmacokinetics model. | 05 |
| | (c) Write note on application of Microcalorimeter in pharmacy. | 05 |
