

GUJARAT TECHNOLOGICAL UNIVERSITY
M.PHARM – SEMESTER -1 - EXAMINATION –WINTER - 2018

Subject Code: 910102**Date: 03/01/2019****Subject Name: Pharmaceutical Formulation Development & Biopharmaceutics****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) | What is preformulation? Discuss importance of preformulation study. | 06 |
| | (b) | Enumerate physicochemical factors influencing preformulation with suitable examples. | 05 |
| | (c) | Discuss the role of crystallinity and polymorphism in dissolution of drug | 05 |
| Q.2 | (a) | Enlist various techniques used for solubility enhancement. Discuss Solid dispersion in detail. | 06 |
| | (b) | Discuss the applications of microcalorimetry in stability study. | 05 |
| | (c) | Describe determination of bioavailability of drug using urinary excretion data. | 05 |
| Q.3 | (a) | Describe significance of <i>IVIVC</i> . Explain methods of establishing <i>IVIVC</i> . | 06 |
| | (b) | Define intrinsic solubility. Discuss a method to determine intrinsic solubility of a drug. | 05 |
| | (c) | Write a note on drug excipients compatibility study. | 05 |
| Q.4 | (a) | Discuss the permeability and active drug transport across CACO-2 monolayers | 06 |
| | (b) | Enumerate types of bioequivalence. Discuss briefly latin-square cross over design. | 05 |
| | (c) | Differentiate real time stability study and accelerated stability study. | 05 |
| Q.5 | (a) | Discuss Physicochemical factors affecting the drug absorption. | 06 |
| | (b) | Explain: Total Clearance, Volume of distribution. | 05 |
| | (c) | Give the details of formulation and evaluation of herbal face wash. | 05 |
| Q. 6 | (a) | Discuss matrixing and bracketing techniques for stability study design | 06 |
| | (b) | What is BCS? Discuss the importance of BCS in dosage form development. | 05 |
| | (c) | Discuss factors affecting on development of <i>IVIVC</i> . | 05 |
| Q.7 | (a) | How dissolution medium is selected for new API? Explain discriminating and bio relevant dissolution media? | 06 |
| | (b) | What is ICH? Discuss different climatic zones in stability study. | 05 |
| | (c) | Explain formulation and evaluation methods of sunscreen lotions. | 05 |
