

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – I • EXAMINATION – WINTER 2013

Subject Code: 910102

Date: 23-12-2013

Subject Name: Pharmaceutical Formulation, Development & 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) | Explain the pre-formulation aspects of crystalline state vs amorphous state and discuss the methods to evaluate this. | 06 |
| | (b) | Outline pre formulation study for any one dosage form using BCS class IV API | 05 |
| | (c) | Justify: DSC is important analytical tool in pre-formulation. | 05 |
| Q.2 | (a) | Discuss the factors affecting selection of dissolution media and conditions for bio relevant media. | 06 |
| | (b) | What is model dependant and in dependant methods to compare dissolution profile? | 05 |
| | (c) | Discuss the methods to improve solubilization. | 05 |
| Q.3 | (a) | Compare accelerated stability study with real time stability study. | 06 |
| | (b) | Write a note on Photo stability study. | 05 |
| | (c) | What is matrixing and bracketing technique for sampling. | 05 |
| Q.4 | (a) | Explain the role of Order of reaction in predicting half-life and shelf-life of the formulation. | 06 |
| | (b) | Explain the importance of Drug-excipient compatibility. | 05 |
| | (c) | Enumerate dental products. Discuss evaluation criteria for these products. | 05 |
| Q.5 | (a) | Discuss the pharmaceutical consideration for CACO2. | 06 |
| | (b) | What is Biowaiver? What is the criteria for this? | 05 |
| | (c) | What do you mean by absorption window? How does it affects formulation and drug delivery? | 05 |
| Q. 6 | (a) | What are the merits and demerits of Wagnor-Nelson Method as compare to Ka? | 06 |
| | (b) | What are limitations and application of method of residuals? | 05 |
| | (c) | What is plasma protein binding? | 05 |
| Q.7 | (a) | What do you mean by levels of IVIVC? | 06 |
| | (b) | Explain clearance is more important parameter then t1/2 or Kel of API | 05 |
| | (c) | What challenges are to be considered by a formulator while manufacturing skin cosmetics for MEN or WOMEN? | 05 |
