

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.

- 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 Wagner-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  $t_{1/2}$  or Kel of API **05**
- (c) What challenges are to be considered by a formulator while manufacturing skin cosmetics for MEN or WOMEN? **05**

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