

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharmacy Sem-I Examination January 2010

Subject code: 910102

Subject Name: Pharmaceutical Formulation, Development & Biopharmaceutics

Date: 23 /01/ 2010

Time: 12.00 – 3.00 pm

Instructions:

Total Marks: 80

1. Attempt any five questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

- Q.1** (a) What is Preformulation? How can it be characterized? **06**
Comment: "Preformulation studies are limited to new drug molecules only". Suggest different means to arrest hydrolysis of APIs.
- (b) How is the particle engineering influence the development of compacted APIs and its compressed dosage form? **05**
- (c) Define polymorphism and pseudo-polymorphism. **05**
Enlist the methods to identify polymorphism.
Comment on dissolution behavior and stability of polymorphs.
- Q.2** (a) What do you mean by intrinsic solubility? **06**
Enlist various solubilization techniques with their mechanisms.
Discuss the importance of B-cyclodextrin utility number and derivation of it.
- (b) Discuss the use of salt-formation, surfactants, adducts and clathrates in solubilization of poorly soluble drugs. **05**
- (c) "Bioavailability of poorly soluble APIs is challenge to formulation pharmacist". Discuss physical and chemical modification of APIs and use of excipients to solve this issue. **05**
- Q.3** (a) What do you mean by dissolution mimicking? **06**
Write a note on Biorelevant media.
- (b) What is super critical fluid technique? **05**
Explain its application in solubilization of APIs and compare its efficiency with other such techniques.
- (c) Discuss the dissolution test for unconventional and novel dosage forms. **05**
- Q.4** (a) Define kinetics. Describe different methods to determine order of reaction. Compare zero, first and second order degradation with emphasizing their utility in stability studies. **06**
- (b) Discuss the requirement related to stability testing with emphasizing matrixing / bracketing technique, climatic zones, impurities and photostabilization. **05**
- (c) How is accelerated stability study carried out? **05**
How the results of it can be correlated with real time study?
- Q.5** (a) Explain the factors affecting gastric emptying. **06**

- How manufacturing variables affect drug absorption? **05**
- (b) Define bioavailability and bioequivalence. **05**
 Enlist methods of measurement of bioavailability.
 Discuss latin-square cross-over design.
- (c) Explain schematic diagram of sequential absorption of oral solids. **05**
 What are the consideration of CACO2 cellline?
- Q. 6** (a) Define biological half-life and volume of distribution. How are they related? **06**
 Explain the effect of drug distribution into tissue on Vd giving suitable illustrations.
 Explain the different routes of clearance.
- (b) What is multi-compartment model? **05**
 Enlist such models and write a note on three compartment model.
- (c) Write a note on non-linear pharmacokinetics. **05**
- Q.7** (a) Define IVIVC & IVIVR. What are the levels of correlation in IVIVC? Suggest different methods and applications of it. **06**
- (b) Calculate the values of similarity and dissimilarity factors for the following data. (Time versus cumulative drug dissolved) **05**
 Time in min 10 20 30 45 60 90 120
 Reference 33.7 51.02 62.38 70.95 79.66 89.89 90.81
 Test 39.61 56.25 66.29 77.79 85.67 89.51 94.57
- (c) Discuss the formulation of cosmetic product used in oral cavity. **05**
