Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M.PHARM- SEM-I–EXAMINATION – JULY 2012

Subject code: 910102 Date: 05/07/2012

Subject Name: Pharmaceutical Formulation, Development & Biopharmaceutics

Time: 02:30 pm – 05:30 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) What is polymorphism? Discuss its significance in dissolution. Enumerate the methods to identify polymorphs. **06**

(b) Describe preformulation study for preparation of oral tablets. **05**

(c) Discuss the considerations of OVIs in preformulation study. **05**

Q.2 (a) Discuss various techniques of drug solubilization with their mechanism. **06**

(b) What is intrinsic solubility? How is it determined? Discuss the difference of intrinsic solubility from dissolution rate. **05**

(c) Write a note on: BCS. **05**

Q.3 (a) Explain Bio-relevant media and Dissolution mimicking. **06**

(b) Discuss the factors affecting the selection dissolution media. **05**

(c) Define sink condition. How it can be achieved? **05**

Q.4 (a) Describe different climatic zones in stability testing. **06**

(b) Discuss the applications of microcalorimetry in stability study. **05**

(c) Calculate dissimilarity and similarity factor for the given CPR data and state whether the products are similar or not? **05**

Time (min)	10	20	30	45	60	90	120
CPR-Ref	42.54	53.46	64.89	72.16	78.51	84.83	87.10
CPR-Test	42.64	55.94	67.31	72.99	81.28	84.15	88.83

Q.5 (a) Discuss the factors affecting drug absorption. **06**

(b) Describe the methods used to determine absorption rate constant and elimination rate constant. **05**

(c) Write a note on: Method of studying bioavailability and bioequivalence. **05**

Q. 6 (a) Explain IVIVC and IVIVR. Describe methods for establishing IVIVC. **06**

(b) Discuss the factors affecting IVIVC. **05**

(c) Explain clearance, apparent volume of distribution and biological half-life. Describe the method of determination of V_d of a new drug. **05**

Q.7 (a) Discuss the Quality Control for Cosmetics. **06**

(b) Describe the methods of evaluation of products containing herbal ingredients. **05**

(c) What is flip-flop phenomenon? Write note on nonlinear pharmacokinetics. **05**

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