Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

B. Pharm. – SEMESTER – VII • EXAMINATION – WINTER 2013

Subject Code: 270001 Date: 26-11-2013

Subject Name: Dosage Form Design-I

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) Enumerate the physical properties affecting preformulation studies in designing a dosage form and discuss any one in details giving suitable illustrations. **08**

(b) Enumerate the chemical properties affecting preformulation studies in designing a dosage form and discuss any one in details giving suitable illustrations. **08**

Q.2 (a) Describe the ideal properties of a preservative. **06**

(b) Write a Note on: Lactose as an ideal diluent. **05**

(c) Discuss the points to be considered for proper selection of color in designing of the dosage form. **05**

Q.3 (a) Discuss the factors affecting stability of pharmaceutical formulation. **06**

(b) Explain the half life and shelf life of a formulation product. How are both determined and expressed? **05**

(c) Discuss the effect of container and closures on stability of pharmaceutical dosage form. **05**

Q.4 (a) Enumerate the factors affecting drug absorption from GIT. Discuss the effect of gastric emptying, drug pKa and GI pH on drug absorption. **06**

(b) Enlist the various mechanism of transport of drug across biological barriers. Discuss any one mechanism in details. **05**

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

Q.5 (a) Discuss the regulatory requirements for conduction of bio-equivalence studies. **06**

(b) From the following blood data obtained after the oral administration of 50 mg of a drug A, calculate the AUC. **05**

Sr. No.	Time in hr	Plasma drug concentration in mcg/ml
1	1	5.5
2	2	9.2
3	3	14.9
4	4	10.3
5	5	7.1
6	6	2.2

(c) Explain the designs of single dose bioequivalence study. **05**

Q. 6 (a) Discuss the factors affecting drug dissolution. **06**

(b) Describe the model independent method for comparison of dissolution profiles. **05**

(c) Calculate dissimilarity and similarity factor for the following drug dissolution 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. 7 (a) What is ICH? Describe different climatic zones in stability testing. **06**

(b) Describe the applications of pro-drug approach in formulation design. **05**

(c) Describe the dissolution apparatus-I of Indian Pharmacopoeia. **05**

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