Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

B. PHARM. - SEMESTER – VII • EXAMINATION – WINTER 2012

Subject code: 270001 Date: 27/12/2012

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)	Define Pre-Formulation study. Enlist techniques used in it. Describe any one of them to ascertain Drug-Excipieent Compatibility.	06
	(b)	Classify additives used in Pharma. Formulations and describe in detail about antimicrobial preservatives.	05
	(c)	Write a note on Polymorphism giving suitable illustration.	05
Q.2	(a)	Define order of reaction. Compare the speed of zero to second order Degradation study with respect to any marker parameter.	06
	(b)	How temperature degradation study are applied to Pharma. Formulations? Derive an equation for half-life and method to establish expiry date and overages in Pharma. Formulation.	05
	(c)	Write a note on container-closure with respect to stability aspect.	05
Q.3	(a)	How the drug is passed through various biological barriers? Write a note on pinocytosis.	06
	(b)	Write a note on factors affecting drug absorption.	05
	(c)	What is a role of protein binding in drug distribution in the body.	05
Q.4	(a)	Write a note on different equivalentces and explain the terms related to Bioavailibility after oral dose.	06
	(b)	What is BCS classification? How does it affects development of dosage form?	05
	(c)	Write a note on Dissolution profile comparison.	05
Q.5	(a)	How Prodrugs are useful in overcoming problems of stability and bioavailability?	06
	(b)	Write a note on matrixing and bracketing techniques.	05
	(c)	A prescription for a liquid Aspirin formulation is called for 325mg/5ml. The solubility of aspirin at 25^0C is 0.33G/100ml. The preparation is suspension and F.O.R. constant for aspirin degradation in this solution is $4.5x10^{-6}$ sec^{-1}. Calculate zero order constant and determine shelf-life	05
Q. 6	(a)	What is intrinsic dissolution rate? Enlist various dissolution apparatus for different dosage forms. Write a note on factors affecting dissolution.	06
	(b)	Write a note on Photo stability study.	05
	(c)	A solution of drug was freshly prepared 300mg/ml and after 30 days it was found to 75mg/ml at 25^0C. (I) Assuming F.O.K. when the drug will decline to half of its original? (II) Assuming Z.O.K. when the drug will decline to half of its original?	05
Q.7	(a)	What is active transport mechanism?	06
	(b)	What is Stability guideline as per ICH?	05
	(c)	Compare Zero and first order degradation in terms of t_0 , t_{50}, and t_{90}.	05

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