Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM – SEMESTER – VII • EXAMINATION – WINTER – 2015

Subject Code: 270001 **Date: 04/12/2015**

Subject Name: Dosage Form Design I

Time: 10.30 AM to 1.30 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 various mechanisms involved in drug absorption. Discuss carrier mediated transport.	**06**
	(b)	Define polymorphism. Explain its importance in preformulation study with example.	**05**
	(c)	Explain oxidative decomposition of pharmaceutical preparations with suitable examples. Describe preventive measures.	**05**
Q.2	(a)	Discuss various approaches for enhancement of bioavailability.	**06**
	(b)	Write a note on stability testing guideline as per ICH for pharmaceutical drug substance and drug product.	**05**
	(c)	What is renal clearance? Explain factors affecting renal clearance.	**05**
Q.3	(a)	Define prodrugs. Discuss pharmaceutical application of prodrugs.	**06**
	(b)	Write a note on climatic zone and MKT.	**05**
	(c)	Enlist various methods for measurement of bioavailability. Explain indirect methods in detail.	**05**
Q.4	(a)	The decomposition of fructose in aqueous acid solution was found to follow first order reaction. The initial concentration was found to be 0.077 M. The concentration after period of 10 hours was found to be 0.068 M. i) Calculate the reaction rate constant. ii) Calculate the quantity of fructose remaining undecomposed after 6 hours. iii) Estimate the amount of fructose lost during period of 24 hours.	**06**
	(b)	Discuss criteria for waiver of *in vivo* bioavailability study with reference to drug product.	**05**
	(c)	Write a note on suspending agents and emulsifiers used in liquid formulations.	**05**
Q.5	(a)	Enlist various physical properties of drug which affect the stability and bioavailability of pharmaceutical formulations. Discuss dielectric constant.	**06**
	(b)	Explain various designs used to perform bioequivalence study.	**05**
	(c)	Enlist various theories of drug dissolution. Discuss film theory and variables affecting drug dissolution.	**05**
Q. 6	(a)	Explain kinetic involved in protein drug binding with description of plots.	**06**
	(b)	Enlist various adjuvants used in preparation of different pharmaceutical products. Discuss disintegrants and antifrictional agents with example.	**05**
	(c)	Write a note on matrixing and bracketing instability study.	**05**
Q.7	(a)	Comment on followings: i) The overages are added to all products in order to maintain 100 percent label amount during expected shelf life. ii) In photochemical reaction light source is considered as catalyst.	**06**
	(b)	Describe accelerated stability study with its limitations.	**05**
	(c)	Enumerate various USP dissolution apparatus and describe type I USP apparatus.	**05**

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