Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM- SEMESTER–VII • EXAMINATION – WINTER-2016

Subject Code: 270001 **Date: 17/11/2016**

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 polymorphism. Explain its importance in preformulation study with example.	**06**
	(b)	Write a brief note on overages.	**05**
	(c)	Describe the Accelerated stability study with its limitation.	**05**
Q.2	**(a)**	Discuss Pharmaceutical application of Prodrug.	**06**
	(b)	Discuss the role of diluents in solid dosage form.	**05**
	(c)	Write a note on Preservatives.	**05**
Q.3	**(a)**	Explain the physicochemical properties of drug substance that affect the absorption of drug.	**06**
	(b)	Write a note on volume of distribution.	**05**
	(c)	Discuss the Photolysis reaction in detail.	**05**
Q.4	**(a)**	Discuss the factor affecting renal clearance.	**06**
	(b)	Describe USP Type-II dissolution apparatus.	**05**
	(c)	Write a note on BCS classification system.	**05**
Q.5	**(a)**	Discuss the effect of container and closures on stability of Pharmaceutical dosage form.	**06**
	(b)	Explain Latin square cross over design in Bioequivalence study.	**05**
	(c)	Discuss the criteria for waivers of in vivo Bioequivalence studies.	**05**
Q. 6	**(a)**	Write a note on Bracketing & matrixing design in stability study.	**06**
	(b)	Write a note on disintegrating agents.	**05**
	(c)	Discuss the role of solubility in Preformulation study.	**05**
Q.7	**(a)**	Write a note on Plasma Protein Drug Binding.	**06**
	(b)	Write a note on similarity factor and difference factor in dissolution profile comparison.	**05**
	(c)	Discuss Drug-Excipients compatibility study in detail	**05**

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