Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 2270001 **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)**	What do you understand by first pass metabolism? How would you avoid it?	**06**
	(b)	Explain LADME. What is the importance of loading dose?	**05**
	(c)	Explain AUC. What is its significance? How will you measure it?	**05**
Q.2	**(a)**	Define i) Bioavailability ii) C_{max} iii) t_{max}	**06**
	(b)	Why "Bioequivalence is covered under regulatory requirements?"	**05**
	(c)	Write a short note on "Plasma Protein Binding".	**05**
Q.3	**(a)**	What is BCS classification? How does it affect development of dosage form?	**06**
	(b)	What is the importance of $t_{1/2}$ in design and development of a dosage form?	**05**
	(c)	Explain a dissolution apparatus. How does it give an idea of dissolution of various dosage form?	**05**
Q.4	**(a)**	What do you understand by adjuvants? How are they utilized in designing innovative dosage forms?	**06**
	(b)	Write a note on 'Biodegradable Polymers'.	**05**
	(c)	Briefly outline the parameters to consider as per ICH guidelines.	**05**
Q.5	**(a)**	What do you understand by prodrug? How do they help in designing a better dosage form?	**06**
	(b)	Enumerate properties of API to be considered before designing its dosage form.	**05**
	(c)	Discuss Matrixing and Bracketing Techniques: Purpose and objective.	**05**
Q. 6	**(a)**	What are the ideal properties of preservatives?	**06**
	(b)	Discuss the effect of containers and closures on stability of pharmaceuticals.	**05**
	(c)	'Lactose is an ideal diluent' Comment.	**05**
Q.7	**(a)**	Effect of pKa and pH on absorption parameter.	**06**
	(b)	*"Hydrophylicity and lipophylicity property of a drug decide its absorption"* Comment with justification.	**05**
	(c)	Explain shelf life and overages briefly. Why are they important for a dosage form?	**05**

****