Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

B. Pharm. – SEMESTER – VII • EXAMINATION – SUMMER • 2014

Subject Code: 270001 Date: 03-06-2014

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 and pseudo-polymorphism. Enlist the methods to identify polymorphism. Comment on dissolution behavior and stability of polymorphs.	**06**
	(b)	What is Preformulation? How can it be characterized? Suggest different means to arrest hydrolysis of APIs.	**05**
	(c)	How is the particle engineering influence the development of compacted APIs and its compressed dosage form?	**05**
Q.2	(a)	Enlist additives used in tablet dosages form. Discuss the anti frictional agents.	**06**
	(b)	Explain term emulsifiers & suspending agent w.r.t. pharmaceutical formulation. Give the classification of emulsifying agents.	**05**
	(c)	Discuss the role of binders in compressed pharmaceutical dosages form.	**05**
Q.3	(a)	Define bioavailability and bioequivalence. Enlist methods of measurement of bioavailability. Discuss latin-square cross-over design.	**06**
	(b)	Give regulatory requirements for conduction of bio-equivalent studies.	**05**
	(c)	What is Gastric emptying? Explain influence of food on drug absorption.	**05**
Q.4	(a)	Enlist various barriers to drug absorption. Describe passive diffusion of drug.	**06**
	(b)	What is biopharmaceutics? Explain its role in formulation development.	**05**
	(c)	Discuss the physiological factor influencing drug absorption.	**05**
Q.5	(a)	Discuss the requirement related to stability testing with emphasizing matrixing/ bracketing technique and climatic zones.	**06**
	(b)	How is accelerated stability study carried out? How the results of it can be correlated with real time study?	**05**
	(c)	Define kinetics. Discuss the order of reaction with respect of stability testing.	**05**
Q. 6	(a)	What is BCS? Give its objectives & classification. Give condition for justifying request of biowaiver.	**06**
	(b)	Enumerates factors affecting dissolution of drug, discuss factors related to drug product formulation.	**05**
	(c)	Give the significance of dissolution profile comparison. Explain similarity factor for dissolution comparison.	**05**
Q. 7	(a)	What are overages? Give its permitted limit. Describe its calculations.	**06**
	(b)	Write note on Plasma protein binding	**05**
	(c)	Discuss the factors affecting on drug formulation stability	**05**

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