Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B. Pharm. - SEMESTER–7 • EXAMINATION – SUMMER -2018

Subject Code: 270001 **Date: 19/5/2018**

Subject Name: Dosage Form Design- I

Time: 02:30 PM TO 05:30 PM **Total Marks: 80**

1. Attempt any five questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

Q.1	(a)	What is intrinsic solubility? How is it measured?	**02**
	(b)	What is partition coefficient? What is its significance in preformulation?	**04**
	(c)	What is photolysis? Describe the means to prevent photodegredation of drugs.	**05**
	(d)	What is por-prodrug? Describe the prodrug design approach for drug targeting with examples.	**05**
Q.2	(a)	What are disintegrants? Name four superdisintegrants?	**02**
	(b)	What are ointments? Describe the different types of suppository bases.	**04**
	(c)	Enumerate additives used in tablets. Discuss tablet binders.	**05**
	(d)	What is flavor? Describe flavors used in liquid formulations.	**05**
Q.3	(a)	Define: Product Shelf Life and Mean Kinetic Temperature.	**02**
	(b)	What is formulation stability? Discuss the different climatic zones for stability testing.	**04**
	(c)	What are overages? How are they calculated? In which formulations are they allowed?	**05**
	(d)	Describe matrixing and bracketing in stability study.	**05**
Q.4	(a)	Explain: Drug Disposition and Dosage Form Design.	**02**
	(b)	What is protein drug binding? Describe displacement drug interactions in protein binding.	**04**
	(c)	What is drug transport? Describe passive diffusion process for drug transport.	**05**
	(d)	Describe the pH Partition theory for drug absorption.	**05**
Q.5	(a)	What is GFR? Which are the markers used to measure it?	**02**
	(b)	Describe Latin Square cross over design for bioequivalence study.	**04**
	(c)	What is suprabioavilability? Describe AUC, Cmax and Tmax as bioavailability measures.	**05**
	(d)	What is absolute and relative bioavailability? Calculate these values for capsule based on given data. Capsule (Dose-200 mg Oral, AUC -40); Solution (Dose-200 mg Oral, AUC-60) and Injection (Dose-100 mg IV bolus, AUC- 100).	**05**
Q. 6	(a)	Explain: Biowaivers.	**02**
	(b)	What is BCS? What is its significance in dosage form design?	**04**
	(c)	What is biorelevant dissolution media? Name the USP dissolution apparatus with the use.	**05**
	(d)	What is dissolution efficiency? Describe dissolution data comparison based on f_1 and f_2.	**05**
Q.7	(a)	What is ICH? Describe the ICH guidelines for stability.	**04**
	(b)	What is BBB? Describe approaches used to target polar drugs to brain.	**04**
	(c)	Describe drug binding to HAS.	**04**
	(d)	What is sink condition? Describe methods to achieve *in vitro* sink condition.	**04**

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