Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM.-SEMESTER–VII- EXAMINATION –SUMMER-2017

Subject Code: 270001 **Date: 27/04/2017**
Subject Name: Dosage Form Design- I
Time: 02:30 PM to 05:30 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)	Discuss effect of pKa of drug on absorption of drug from GIT at different pH.	**06**
	(b)	Write a note on Polymorphism giving examples.	**05**
	(c)	Explain mutual prodrugs. Describe the prodrug design for improvement of stability and bioavailability giving suitable examples.	**05**
Q.2	(a)	Discuss different approaches for prevention of chemical degradation of pharmaceuticals.	**06**
	(b)	Define Mean Kinetic Temperature (MKT). Discuss different climatic zones for stability studies.	**05**
	(c)	What are temperature and humidity requirements for performing stability study according to ICH guideline?	**05**
Q.3	(a)	Write brief note on factors affecting plasma protein binding.	**06**
	(b)	Why overages are added in formulation? How it can be calculated?	**05**
	(c)	Discuss physiological barriers for distribution of drugs.	**05**
Q.4	(a)	Define biopharmaceutics and give its role in dosage form desing.	**06**
	(b)	Enumerate different types of transport mechanism. Explain active transport in detail.	**05**
	(c)	Define gastric empting and explain factors affecting gastric empting.	**05**
Q.5	(a)	Write detail note on organoleptic additives.	**06**
	(b)	Classify stabilizers and write their pharmaceutical applications.	**05**
	(c)	Classify suspending agents. What are ideal characteristics of suspending agent?	**05**
Q. 6	(a)	Enlist methods of dissolution profile comparison Discuss in detail model independent method.	**06**
	(b)	What is BCS? How BCS class of a drug is decided?	**05**
	(c)	Define Intrinsic dissolution rate. Discuss factors affecting rate of dissolution.	**05**
Q.7	(a)	What are the objectives of bioavailability study? Explain measurement of bioavailability by Plasma level-time study.	**06**
	(b)	What is therapeutic equivalence? Enlist various *in-vivo* and *in-vitro* approaches that can be utilized to establish bioequivalence.	**05**
	(c)	Differentiate absolute and relative bioavailability. What are the acceptance criteria for bioequivalence study?	**05**

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