Seat No.: _____ Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

B.PHARM - SEMESTER– 7 EXAMINATION – SUMMER -2020

Subject Code: 2270001 **Date:26-10-2020**

Subject Name: Dosage form Design I

Time: 2:30 PM TO 5:30 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 Pre-Formulation study. Enlist techniques used in it. Describe any one of them to ascertain Drug-Excipient Compatibility.	**06**
	(b)	Explain the influence of chemical properties of drugs on formulation and stability of the products.	**05**
	(c)	Explain: 1) Overages 2) Climatic Zones.	**05**
Q.2	**(a)**	Discuss Effect of physical properties of drug like physical form, particle size and shape on formulation, stability and bioavailability.	**06**
	(b)	Enlist additives used in tablet dosages form. Discuss the anti frictional agents.	**05**
	(c)	Write a note on prodrugs.	**05**
Q.3	**(a)**	Classify additives used in pharmaceutical formulations. Describe in detail about suspending agents.	**06**
	(b)	Discuss stability testing of new drug substances and products as per ICH Guideline.	**05**
	(c)	Explain the characteristics of Active transport process. Write their application in the development of formulation and administration of drugs.	**05**
Q.4	**(a)**	Discuss the factors affecting stability of pharmaceutical formulation.	**06**
	(b)	Describe Matrixing and bracketing in stability study.	**05**
	(c)	What is IVIVC? Describe In-vitro - In-vivo correlations levels.	**05**
Q.5	**(a)**	Enumerate the factors affecting drug absorption from GIT. Discuss the effect of gastric emptying, drug pKa and GI pH on drug absorption.	**06**
	(b)	Discuss plasma protein drug binding.	**05**
	(c)	Enumerate the drug transport mechanisms. Discuss passive diffusion in detail.	**05**
Q. 6	**(a)**	Write a note on similarity factor and dissimilarity factor.	**06**
	(b)	Classify the methods for bioavailability measurement. Discuss the method based on plasma data.	**05**
	(c)	Define absolute and relative bioavailability. Describe Latin Square cross over design for bioequivalence study.	**05**
Q.7	**(a)**	What is BCS? Classify and give the significance of this system	**06**
	(b)	Discuss the factors affecting drug dissolution.	**05**
	(c)	Explain USP dissolution apparatus III, IV and V with diagram.	**05**

****