Seat No.: _____ **Enrolment No._____**

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm Semester –I Examination Feb. - 2012

Subject code: 910102 **Date: 13/02/2012**

Subject Name: Pharmaceutical Formulation Development & Biopharmaceutics

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)	Discuss perspective and concepts of preformulation study	**06**
	(b)	What is crystal morphology? Discuss rational for selecting the preferred polymorph or crystalline form	**05**
	(c)	Write Winsor's theory of solubilization	**05**
Q.2	(a)	Give an applications of Differential scanning calorimetry and FTIR in preformulation study	**06**
	(b)	Enumerate techniques for improvement in drug solubiliztion and discuss host-guest relationship of inclusion complex	**05**
	(c)	Describe the influence of solvents and surfactants on solubility	**05**
Q.3	(a)	Discuss comparison of dissolution profile by computer modeling	**06**
	(b)	Discuss matrixing designs for stability testing of new drug products	**05**
	(c)	Discuss selection of dissolution medium and conditions	**05**
Q.4	(a)	Discuss basic concept and objectives of stability testing	**06**
	(b)	Discuss permeability and active drug transport across CACO-2 monolayers	**05**
	(c)	Discuss the general regulatory requirements of stability testing	**05**
Q.5	(a)	How toothpaste is evaluated?	**06**
	(b)	Discuss importance of volume of distribution and plasma protein binding	**05**
	(c)	Write significance and importance of BCS	**05**
Q. 6	(a)	What is nonlinear pharmacokinetics? Discuss problems in qualifying nonlinear pharmacokinetics	**06**
	(b)	Give physicochemical factors affecting to the drug absorption	**05**
	(c)	Give bioequivalence study requirements	**05**
Q.7	(a)	Define drug distribution. Distribution of a drug not uniform throughout the body-comment	**06**
	(b)	Write a note on methods of establishing IVIVC	**05**
	(c)	Give relevant testing of herbal products used to treat infections	**05**

****