

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.

<b>Q.1</b>	(a) Discuss perspective and concepts of preformulation study	<b>06</b>
	(b) What is crystal morphology? Discuss rational for selecting the preferred polymorph or crystalline form	<b>05</b>
	(c) Write Winsor's theory of solubilization	<b>05</b>
<b>Q.2</b>	(a) Give an applications of Differential scanning calorimetry and FTIR in preformulation study	<b>06</b>
	(b) Enumerate techniques for improvement in drug solubilization and discuss host-guest relationship of inclusion complex	<b>05</b>
	(c) Describe the influence of solvents and surfactants on solubility	<b>05</b>
<b>Q.3</b>	(a) Discuss comparison of dissolution profile by computer modeling	<b>06</b>
	(b) Discuss matrixing designs for stability testing of new drug products	<b>05</b>
	(c) Discuss selection of dissolution medium and conditions	<b>05</b>
<b>Q.4</b>	(a) Discuss basic concept and objectives of stability testing	<b>06</b>
	(b) Discuss permeability and active drug transport across CACO-2 monolayers	<b>05</b>
	(c) Discuss the general regulatory requirements of stability testing	<b>05</b>
<b>Q.5</b>	(a) How toothpaste is evaluated?	<b>06</b>
	(b) Discuss importance of volume of distribution and plasma protein binding	<b>05</b>
	(c) Write significance and importance of BCS	<b>05</b>
<b>Q. 6</b>	(a) What is nonlinear pharmacokinetics? Discuss problems in qualifying nonlinear pharmacokinetics	<b>06</b>
	(b) Give physicochemical factors affecting to the drug absorption	<b>05</b>
	(c) Give bioequivalence study requirements	<b>05</b>
<b>Q.7</b>	(a) Define drug distribution. Distribution of a drug not uniform throughout the body-comment	<b>06</b>
	(b) Write a note on methods of establishing IVIVC	<b>05</b>
	(c) Give relevant testing of herbal products used to treat infections	<b>05</b>

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