Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharmacy Sem-I Regular / Remedial Examination January/February 2011

Subject code: 910102

Subject Name: Pharmaceutical Formulation Development & Biopharmaceutics

Date: 31 /01 /2011 **Time: 10.30 am – 01.30 pm**

Instructions: **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) Define preformulation. What is the significance of particle size & size distribution in formulation? **06**

(b) What is polymorphism? What is its significance in dissolution and patenting? Name the methods to identify polymorphs. **05**

(c) How the preformulation studies for biotechnologically derived products are carried out? **05**

Q.2 (a) What is intrinsic solubility? How is it determined? How intrinsic solubility differs from dissolution rate? **06**

(b) Discuss various techniques for drug solubilization with mechanisms. **05**

(c) Describe B-cyclodextrin complexation for dissolution improvement. **05**

Q.3 (a) What is the significance of dissolution testing? Describe dissolution test for unconventional and novel dosage forms. **06**

(b) How dissolution medium is selected for new API? Explain discriminating and biorelevant dissolution media. **05**

(c) Calculate dissimilarity & similarity factor for the given data and state whether the products are similar or not? **05**

Disso. time (min)	15	30	45	60	90	120
CPR - Reference	41.3	57.4	69.2	78.1	86.1	92.8
CPR- Test	42.6	58.5	69.1	78.2	88.2	91.3

Q.4 (a) What is formulation stability? Describe various means of formulation stabilization. **06**

(b) Discuss accelerated stability study and its correlation with real time stability study? **05**

(c) What is ICH? Describe different climatic zones in stability testing. **05**

Q.5 (a) Discuss factors affecting gastric emptying. Describe conditions in which rapid and delayed gastric emptying is desired? **06**

(b) What is suprabioavailability? Enlist methods for bioavailability measurement and describe method based on plasma drug data. **05**

(c) Which are different cell lines used for absorption study? Describe method based on CaCo2 cell line. **05**

Q. 6 (a) Explain clearance, apparent Vd, biological half-life. How are they related? How the Vd of the new drug is determined? **06**

(b) Write note on nonlinear pharmacokinetics. **05**

(c) What is compartment? Describe feathering technique for absorption kinetics. **05**

Q.7 (a) Explain IVIVC & IVIVR. Describe methods for establishing IVIVC. **06**

(b) What are the objectives of IVIVC? Describe different levels of correlation for IVIVC. **05**

(c) Classify cosmetics. Describe cosmetics for sun protection. **05**

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