Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharmacy Sem-I Examination January 2010

Subject code: 910102

Subject Name: Pharmaceutical Formulation, Development & Biopharmaceutics

Date: 23 /01/ 2010 **Time: 12.00 – 3.00 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)	What is Preformulation? How can it be characterized? Comment: "Preformulation studies are limited to new drug molecules only". Suggest different means to arrest hydrolysis of APIs.	**06**
	(b)	How is the particle engineering influence the development of compacted APIs and its compressed dosage form?	**05**
	(c)	Define polymorphism and pseudo-polymorphism. Enlist the methods to identify polymorphism. Comment on dissolution behavior and stability of polymorphs.	**05**
Q.2	(a)	What do you mean by intrinsic solubility? Enlist various solubilization techniques with their mechanisms. Discuss the importance of B-cyclodextrin utility number and derivation of it.	**06**
	(b)	Discuss the use of salt-formation, surfactants, adducts and clathrates in solubilization of poorly soluble drugs.	**05**
	(c)	"Bioavailability of poorly soluble APIs is challenge to formulation pharmacist". Discuss physical and chemical modification of APIs and use of excipients to solve this issue.	**05**
Q.3	(a)	What do you mean by dissolution mimicking? Write a note on Biorelavant media.	**06**
	(b)	What is super critical fluid technique? Explain its application in solubilization of APIs and compare its efficiency with other such techniques.	**05**
	(c)	Discuss the dissolution test for unconventional and novel dosage forms.	**05**
Q.4	(a)	Define kinetics. Describe different methods to determine order of reaction. Compare zero, first and second order degradation with emphasizing their utility in stability studies.	**06**
	(b)	Discuss the requirement related to stability testing with emphasizing matrixing / bracketing technique, climatic zones, impurities and photostabilization.	**05**
	(c)	How is accelerated stability study carried out? How the results of it can be correlated with real time study?	**05**
Q.5	(a)	Explain the factors affecting gastric emptying.	**06**

How manufacturing variables affect drug absorption?

(b) Define bioavailability and bioequivalence. **05**
Enlist methods of measurement of bioavalibility.
Discuss latin-square cross-over design.

(c) Explain schematic diagram of sequential absorption of oral solids. **05**
What are the consideration of CACO2 cellline?

Q. 6 (a) Define biological half-life and volume of distribution. How are they related? **06**
Explain the effect of drug distribution into tissue on Vd giving suitable illustrations.
Explain the different routes of clearance.

(b) What is multi-compartment model? **05**
Enlist such models and write a note on three compartment model.

(c) Write a note on non-linear pharmacokinetics. **05**

Q.7 (a) Define IVIVC & IVIVR. What are the levels of correlation in IVIVC? Suggest different methods and applications of it. **06**

(b) Calculate the values of similarity and dissimilarity factors for the following data. (Time versus cumulative drug dissolved) **05**

Time in min	10	20	30	45	60	90	120
Reference	33.7	51.02	62.38	70.95	79.66	89.89	90.81
Test	39.61	56.25	66.29	77.79	85.67	89.51	94.57

(c) Discuss the formulation of cosmetic product used in oral cavity. **05**

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