Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. IST Semester Examination – June- 2011

Subject code: 910104

Subject Name: Biological evaluations and Clinical Research

Date:22/06/2011 **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)**	What is drug regulation? Describe phases of clinical trials.	**06**
	(b)	Describe Helsinki declaration for clinical trial.	**05**
	(c)	Discuss responsibilities, composition and functions of independent ethical committee.	**05**
Q.2	**(a)**	Discuss bioavailability study for orally administered drug.	**06**
	(b)	What is bioavailability and bioequivalence? Explain. Enlist the methods for conducting BA and BE study.	**05**
	(c)	Describe briefly the special considerations for BA and BE study of modified release drug product.	**05**
Q.3	**(a)**	What is pharmacokinetic? Give its objectives. Define Cmax, tmax and AUC.	**06**
	(b)	What do you mean by pharmacokinetic models? Give its uses. Enlist the approaches to study the pharmacokinetic of drug.	**05**
	(c)	Describe one compartment open model for i.v. bolus administration.	**05**
Q.4	**(a)**	Describe rabbit pyrogen test.	**06**
	(b)	What is pyrogens? Give suitable classification of pyrogens. Describe its physical property.	**05**
	(c)	Describe membrane filtration method of sterility testing for aqueous solutions and suspensions.	**05**
Q.5	**(a)**	What is bioassay? Describe principle, objectives and importance of bioassay.	**06**
	(b)	Discuss design of bioassay with its advantages and disadvantages.	**05**
	(c)	Describe briefly parallel line assay model.	**05**
Q. 6	**(a)**	What is toxicity? Discuss general methodology for toxicology.	**06**
	(b)	Discuss the methods used for microbial assessment of air.	**05**
	(c)	What are biological sample? Describe briefly pretreatment of biological sample.	**05**
Q.7	**(a)**	What is radio immunoassay? Describe its principle scope and limitations.	**06**
	(b)	Describe briefly the tests for effectiveness of antimicrobial preservatives.	**05**
	(c)	Describe FDA validation guideline for LAL test.	**05**

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