Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M.PHARM- SEM-I–EXAMINATION – JULY 2012

Subject code: 910104 **Date: 05/07/2012**

Subject Name: Biological evaluation and Clinical Research

Time: 02:30 pm – 05:30 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 are pyrogens? Describe the chemistry and biological effects of pyrogens.	**06**
	(b)	Describe the principle of LAL test. Give its advantages and disadvantages.	**05**
	(c)	Describe Gel-Clot technique for LAL test.	**05**
Q.2	(a)	Describe membrane filtration method for sterility test.	**06**
	(b)	What is sterility test? Give its principle, objectives and limitations.	**05**
	(c)	Describe direct inoculation method for sterility testing for aqueous and nonaqueous solutions.	**05**
Q.3	(a)	What is bioassay? Give its principle. Describe slope-ratio model of bioassay.	**06**
	(b)	Describe methods used for the evaluation of bioassay.	**05**
	(c)	Describe radio-immuno assay of insulin.	**05**
Q.4	(a)	What is toxicity study? Describe briefly the parameters for measuring toxic effect.	**06**
	(b)	Discuss acute toxicity.	**05**
	(c)	Explain LD_{50} and ED_{50}. Describe method for their determination.	**05**
Q.5	(a)	Describe objectives and study design of clinical trials.	**06**
	(b)	Discuss clinical trial protocol.	**05**
	(c)	Describe briefly Good clinical practices.	**05**
Q. 6	(a)	Explain: Pharmacokinetic, bioavailability and bioequivalence. How the BA and BE is assessed?	**06**
	(b)	Give importance of bioequivalence study. Describe briefly design and conduct of bioequivalence.	**05**
	(c)	Describe one compartment open model- intravenous infusion	**05**
Q.7		Write short notes on the following: a. Extraction of drugs from biological matrix b. Microbial limit test c. Depyrogenation	**16**

****