Seat No.: _____ *Enrolment No._____*

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject code: 910104

Subject Name: Biological Evaluation and Clinical Research

Date: 31 /01 /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 biological standardization? Give its importance. Describe parallel–line model of bioassay.	**06**
	(b)	Explain importance of Student's t-test in Bio-assay.	**05**
	(c)	Discuss preliminary treatment of biological samples for analysis of drug.	**05**
Q.2	(a)	Write in detail about scope and limitation of bio-assay method.	**06**
	(b)	Enumerate tests for effectiveness of antimicrobial preservatives and describe any one.	**05**
	(c)	Discuss ELISA for protein hormones.	**05**
Q.3	(a)	Outline models for Analgesic activity and Anti-inflammatory activity and limitation of such models.	**06**
	(b)	Briefly discuss genetic and Transgenic animal models.	**05**
	(c)	Describe bio assay of Oxytoxin or d-tubocurarin	**05**
Q.4	(a)	Give method of sterilzation any two of followings; [1] Implants [2] Insulin [3] Catgut.	**06**
	(b)	Why is test for bacteriostasis and fungistasis carried out before sterility testing? Describe method A of sterility testing.	**05**
	(c)	Regulatory aspects of bio-availability and bioequivalence studies for controlled drug delivery systems.	**05**
Q.5	(a)	Describe chemical properties of pyrogen and endotoxines.	**06**
	(b)	Describe the LAL test for pyrogens.	**05**
	(c)	Compare validity of Rabbit and LAL test for pyrogens.	**05**
Q. 6	(a)	Write a note on design of clinical research protocol.	**06**
	(b)	How is acute and chronic toxicity studies carried out?	**05**
	(c)	Discuss the study of mutagenicity.	**05**
Q.7	(a)	Discus application of pharmacokinetic in New Drug Development.	**06**
	(b)	Define: Pharmaceutical equivalents, pharmaceutical substitution and pharmaceutical alternatives.	**05**
	(c)	Absorption rate constant is generally greater than elimination rate constant with most drugs, Explain.	**05**

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