Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – I • EXAMINATION – WINTER • 2015

Subject Code: 910104 **Date: 31-12-2015**

Subject Name: Biological Evaluations and Clinical Research

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 Bioassay? Discuss their scope and limitation over other assay methods	**06**
	(b)	Describe bioassay of oxytoxin.	**05**
	(c)	What is radio immunoassay? Describe radioimmunoassay of insulin.	**05**
Q.2	**(a)**	What is sterility testing? Describe membrane filtration method of sterility testing for oil and oily solutions	**06**
	(b)	Describe Direct inoculation method of sterility testing for aqueous solutions and suspensions.	**05**
	(c)	What are acute and sub acute toxicity studies? How are they Performed?	**05**
Q.3	**(a)**	Enlist methods used for monitoring of endotoxin in pharmaceutical product and explain any one in detail.	**06**
	(b)	What is pyrogen? Describe chemistry and properties of pyrogens.	**05**
	(c)	Describe the procedure and interpretation of Sham test.	**05**
Q.4	**(a)**	Explain LD50, ED50, teratogenicity and mutagenicity.	**06**
	(b)	Describe solid phase extraction method for extraction of drug from biological samples	**05**
	(c)	What are biological samples? Give types and collection methods for biological samples	**05**
Q.5	**(a)**	Describe procedure and interpretation for test of effectiveness of antimicrobial preservatives.	**06**
	(b)	Explain objectives and principles of GCP as per ICH guideline.	**05**
	(c)	Write a note on Helsinki declaration.	**05**
Q. 6	**(a)**	What is clinical research protocol? Describe its content.	**06**
	(b)	What are duties and responsibility of the Independent Ethics Committee?	**05**
	(c)	Enlist the methods for conducting BA and BE study and explain any one.	**05**
Q.7	**(a)**	What is pharmacokinetic? Discuss application of pharmacokinetic study in new drug development.	**06**
	(b)	Describe one compartment open model for intravenous infusion.	**05**
	(c)	Explain Bioavailability and bioequivalence. Describe importance of bioequivalence studies.	**05**

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