Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – I • EXAMINATION – WINTER • 2014

Subject Code: 910104 Date: 07-01-2015

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)**	Describe principle of GCP as per ICH guideline.	**06**
	(b)	Discuss ELISA for protein hormones.	**05**
	(c)	Explain importance and clinical significance of Student's t-test in Bio-assay.	**05**
Q.2	**(a)**	What is toxicity? Discuss general methodology for toxicology.	**06**
	(b)	Describe Gel-Clot technique for LAL test.	**05**
	(c)	Write a short note on Helsinki declaration.	**05**
Q.3	**(a)**	Describe advantages of urinary excretion studies. Explain also the criteria for obtaining valid urinary excretion data.	**06**
	(b)	Describe microbial limit tests with its applications.	**05**
	(c)	Describe radio-immunoassay of insulin.	**05**
Q.4	**(a)**	Enumerate various techniques for depyrogenations. Explain any two techniques in details.	**06**
	(b)	What is toxicity study? Describe briefly the parameters for measuring toxic effect.	**05**
	(c)	Enumerate different biological methods in Pharmaceutical Analysis.	**05**
Q.5	**(a)**	Explain, classify and give uses of pharmacokinetic models.	**06**
	(b)	Describe chemical properties of pyrogens and endotoxins.	**05**
	(c)	Describe Indian guidelines on biomedical research and clinical trials.	**05**
Q. 6	**(a)**	Write a note on design, approval and execution of protocol for bioequivalence studies.	**06**
	(b)	Describe the significance and methods used for testing effectiveness of antimicrobial preservatives.	**05**
	(c)	Explain in detail about Protein precipitation method used in various studies.	**05**
Q.7	**(a)**	Write a note on Module 4 and Module 5 of CTD describing non-clinical study reports and clinical study reports.	**06**
	(b)	Describe in detail about Objectives and consideration in bio-availability studies.	**05**
	(c)	Explain LD_{50} and ED_{50}. Describe method for their determination.	**05**

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