Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – I • EXAMINATION – WINTER 2013

Subject Code: 910104 Date: 23-12-2013

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 biological standardization? Give its importance. Describe Parallel–line model of bioassay.	**06**
	(b)	Describe principle of GCP as per ICH guideline.	**05**
	(c)	Describe briefly design and conduct of bioequivalence.	**05**
Q.2	(a)	Discuss the methods used for microbial assessment of air.	**06**
	(b)	Discuss about the LAL test for pyrogens.	**05**
	(c)	Discuss about the source, chemistry, and usual limits of endotoxins in pharmaceutical articles.	**05**
Q.3	(a)	Describe briefly the special considerations for BA and BE study of modified release drug product	**06**
	(b)	Write in detail about scope and limitation of bio-assay method.	**05**
	(c)	Briefly discuss genetic and Transgenic animal models.	**05**
Q.4	(a)	Explain importance of Student's t-test in Bio-assay.	**06**
	(b)	Describe bio assay of Oxytoxin or d-tubocurarin	**05**
	(c)	What is radio immunoassay? Describe its principle. Give its advantages and limitations.	**05**
Q.5	(a)	Discuss about the radioimmunoassay of Insulin.	**06**
	(b)	Describe one compartment open model- intravenous infusion	**05**
	(c)	Discuss about extraction of drugs by SPE method.	**05**
Q. 6	(a)	What is pharmacokinetic? Give its objectives. Define Cmax, tmax and AUC.	**06**
	(b)	Describe Helsinki declaration for clinical trial.	**05**
	(c)	Describe membrane filtration method of sterility testing for aqueous solutions and suspensions.	**05**
Q.7	(a)	Enumerate tests for effectiveness of antimicrobial preservatives and describe any one.	**06**
	(b)	Write a note on design of clinical research protocol	**05**
	(c)	How is acute and chronic toxicity studies carried out?	**05**

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