Seat No.: _____ *Enrolment No. _____*

GUJARAT TECHNOLOGICAL UNIVERSITY

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

Subject Code: 910104 Date: 21-05-2015

Subject Name: Biological Evaluations 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 is bio-assay? Describe the method used for the evaluation of bio-assay.	**06**
	(b)	Describe radio-immuno assay of Insulin.	**05**
	(c)	Describe briefly ELISA test.	**05**
Q.2	**(a)**	What is toxicity study? Describe briefly the parameters for measuring toxic effect.	**06**
	(b)	Describe LAL test for pyrogens.	**05**
	(c)	Describe toxicity testing of plastic container for ophthalmic preparations.	**05**
Q.3	**(a)**	Enumerate the tests for effectiveness of antimicrobial preservatives and Explain any one in detail.	**06**
	(b)	Describe membrane filtration method of sterility testing for aqueous solutions.	**05**
	(c)	What is sterility test? Give its principle, objectives and limitations.	**05**
Q.4	**(a)**	Describe the principle of GCP as per ICH guidelines.	**06**
	(b)	Discuss clinical trial protocol.	**05**
	(c)	Discuss the responsibilities, composition and functions of Institutional Review Board.	**05**
Q.5	**(a)**	Explain pharmacokinetic, bioavailability and bioequivalence.	**06**
	(b)	Describe the criteria for obtaining valid urinary excretion data.	**05**
	(c)	Describe one compartment open model for intravenous infusion.	**05**
Q. 6	**(a)**	Give the importance of drug regulation.	**06**
	(b)	What is drug development? Give different stages of drug development.	**05**
	(c)	Explain briefly about investigator, sponsor and informed consent.	**05**
Q.7	**(a)**	Write a note on Bio-waiver.	**06**
	(b)	Explain the Helsinki declaration for clinical trials.	**05**
	(c)	Write about the extraction of drugs from biological matrix by SPE method.	**05**

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