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