Seat No.:	Enrolment No.

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm - SEMESTER-I • EXAMINATION - WINTER-2016

Subject Code:910104	Date: 02/01/2017
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Subject Name: Biological Evaluations and Clinical Research

 $Time: 10.30 \ AM - 01.30 \ PM \qquad \qquad Total \ Marks: 80$

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 sterility testing? Describe membrane filtration method for the assessment of sterility of liquids.	06
	(b) (c)	Enlist Depyrogenation techniques. Discuss ANY TWO in detail. Write a note on LAL test for detection of pyrogens.	05 05
Q.2	(a) (b)	What is bioassay? Describe the methods for evaluation of Bioassay. Discuss the objective and importance of Bioassay. Explain bioassay of Oxytocin.	06 05
	(c)	What is Radioimmunoassay? Discuss Radioimmunoassay of Insulin.	05
Q.3	(a) (b)	What are clinical trials? Discuss different phases of Clinical trials. Explain the role of Institutional Review Board and Investigator in Good Clinical Practice guidelines.	06 05
	(c)	Write a note on Helsinki Declaration.	05
Q.4	(a) (b)	Write a note on Extraction of drugs from biological matrix. What are biological samples? Give types and collection methods for biological samples.	06 05
	(c)	Describe chemistry of pyrogens and endotoxins. Explain mechanism of action of pyrogens.	05
Q.5	(a)	Define: Bioavailability and Bioequivalence. Explain Urinary excretion method used for measurement of bioavailability.	06
	(b) (c)	Discuss in vitro methods for the assessment of bioavailability. Discuss different Bioequivalence study design and protocol in detail.	05 05
Q. 6	(a)	Explain the terms C_{max} , t_{max} , AUC and V_d . Discuss the Importance of Pharmacokinetic study.	06
	(b)	What are Pharmacokinetic models? Discuss advantages of compartment models and Explain Mammillary model in detail.	05
	(c)	Write a note on Study of Teratogenicity and Mutagenicity.	05
Q.7	(a) (b)	Explain Chronic and sub acute toxicity studies in detail. What is the significance of microbial limit test? Describe methods for testing effectiveness of preservatives.	06 05
	(c)	Describe One compartment open model i.v. bolus administration.	05
