Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. PHARM - SEMESTER– I –EXAMINATION – SUMMER 2017

Subject Code:910104 **Date: 29/04/2017**

Subject Name: Biological Evaluations & Clinical Research

Time:10:30 AM to 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)**	Define and explain biological standardization? Give its importance. Describe Parallel-line model of bioassay.	**06**
	(b)	State and explain microbial limit tests with its applications.	**05**
	(c)	Give brief note on ELISA for protein hormones.	**05**
Q.2	**(a)**	Describe the LAL test for pyrogens.	**06**
	(b)	Describe various parameters employed in bioanalytical method development and validation.	**05**
	(c)	Write in brief about application of pharmacokinetic in New Drug Development.	**05**
Q.3	**(a)**	Describe RIA of insulin in brief.	**06**
	(b)	Write a note on design, approval and execution of protocol for bioequivalence studies.	**05**
	(c)	Explain the scope and contents of Good Laboratory Practices in pre- clinical studies.	**05**
Q.4	**(a)**	Describe methods used for the evaluation of bioassay.	**06**
	(b)	Describe chemical properties of pyrogen and endotoxines.	**05**
	(c)	Write a note on evolution of Good Clinical Practices.	**05**
Q.5	**(a)**	State and explain radio immunoassay? Describe its principle. Give its advantages and limitations.	**06**
	(b)	Write a note on Module 4 and Module 5 of CTD describing non-clinical study reports and clinical study reports.	**05**
	(c)	Describe one compartment open model-intravenous infusion.	**05**
Q. 6	**(a)**	Explain: Pharmacokinetic, bioavailability, bioequivalence and steady state.	**06**
	(b)	Describe the significance, methods and limitations of sterility test in Pharmaceutical analysis.	**05**
	(c)	Discuss LD50 and ED50. Describe method for their determination.	**05**
Q.7	**(a)**	Give brief note on design of clinical research protocol.	**06**
	(b)	Give method of sterilization any two of followings; [1] Implants [2] Insulin [3] Catgut.	**05**
	(c)	What is toxicity study? Describe briefly the parameters for measuring toxic effect.	**05**

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