Seat No.: _____ **Enrolment No._____**

GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm Semester –I Examination Feb. - 2012

Subject code: 910104 **Date: 13/02/2012**

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)	Describe the significance, methods and limitations of sterility test in pharmaceutical analysis.	**06**
	(b)	Describe the source, chemistry, properties and usual limits of endotoxins in pharmaceutical articles.	**05**
	(c)	Describe the scope and advantages of bacterial endotoxin test versus pyrogen test.	**05**
Q.2	(a)	Describe the scope of microbial limit tests in analysis of drug substance and drug products.	**06**
	(b)	Write formula and calculation used in estimation of potency in microbiological assay of antibiotics.	**05**
	(c)	Describe the significance and methods used for testing effectiveness of antimicrobial preservatives.	**05**
Q.3	(a)	Discuss sample preparations for biopharmaceutical analysis of drugs in blood.	**06**
	(b)	Describe various parameters employed in bioanalytical method development and validation.	**05**
	(c)	Write a note on principle, applications and limitations of radio immuno assay in pharmaceutical analysis.	**05**
Q.4	(a)	Enumerate different biological methods in pharmaceutical analysis.	**06**
	(b)	Give the advantages and disadvantages of bioassays compared to other methods of analysis.	**05**
	(c)	Give the details of bioassay of any one drug as per pharmacopoeal procedure.	**05**
Q.5	(a)	Write a note on evolution of Good Clinical Practices.	**06**
	(b)	Enumerate different GCP guidelines and explain the scope and basic objectives of the guidelines.	**05**
	(c)	Describe Indian guidelines on biomedical research and clinical trials.	**05**
Q. 6	(a)	Write the significance of single dose and repeated dose toxicity studies.	**06**
	(b)	Explain the teratogenic toxicity of drugs giving suitable examples.	**05**
	(c)	Explain the scope and contents of Good Laboratory Practices in pre-	**05**

clinical studies.

Q.7	(a)	Write a note on design, approval and execution of protocol for bioequivalence studies.	**06**
	(b)	Define Absolute and relative bioavailability. Explain the parameters considered in establishment of bioequivalence.	**05**
	(c)	Write a note on Module 4 and Module 5 of CTD describing non-clinical study reports and clinical study reports.	**05**

****