Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm. – SEMESTER – I • EXAMINATION – SUMMER 2013

Subject Code: 910104 Date: 15-05-2013

Subject Name: Biological Evaluation 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)**	Explain objective and principles of GCP as per ICH guideline and describe briefly various considerations to be taken before, during and after initation of clinical study.	**06**
	(b)	Explain composition, functions, operations and responsibilities of IRB/IEC.	**05**
	(c)	Write a brief note on clinical research protocol.	**05**
Q.2	**(a)**	Write short notes on: 1. Objectives and importance of bioassay. 2. Interpretation of sterility testing.	**06**
	(b)	Describe bioassay method for oxytocin in detail.	**05**
	(c)	What is sterility testing. Describe membrane filtration method.	**05**
Q.3	**(a)**	Answer the following: 1. Write a brief note on depyrogenation technique. 2. Explain principle, advantages and limitations of radioimmunoassay.	**06**
	(b)	Write a detailed note on bacterial endotoxin.	**05**
	(c)	Explain in detail radioimmunoassay method for digitalis.	**05**
Q.4	**(a)**	Explain significance of microbiological limit test and describe method A for antibiotics according to IP 2010.	**06**
	(b)	Enlist methods for testing effectiveness of antimicrobial preservative and describe any one in detail.	**05**
	(c)	Explain the significance of bioequivalence study. Also briefly describe various designs of bioequivalence study.	**05**
Q.5	**(a)**	Explain various general considerations for designing acute and sub acute toxicity studies according to OECD guidelines.	**06**
	(b)	Explain the terms: mutagenicity, teratogenicity, investigator, informed consent, serious adverse event	**05**
	(c)	Explain the importance of preclinical drug evaluation and how will you determine LD50 and ED50 for a drug?	**05**
Q. 6	**(a)**	Explain the terms: Cmax, tmax, apparent volume of distribution, absolute bioavailability, pharmaceutical equivalent, and pharmaceutical alternative.	**06**
	(b)	Explain the role and significance of bioanalysis in pharmacy. What are the major objectives to be considered for bioanalytical sample preparation?	**05**
	(c)	Enlist various sample preparation techniques in bioanalysis and explain solid phase extraction method in detail.	**05**
Q.7	**(a)**	What is pharmacokinetics. Explain the objective and application of pharmacokinetics in new drug development process.	**06**
	(b)	Explain in detail non linear pharmacokinetics. Also differentiate linear and non-linear models.	**05**
	(c)	Enlist various methods used for determination of bio-availability. Explain urinary excretion method along with advantages.	**05**

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