Seat No.:	Enrolment No.
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GUJARAT TECHNOLOGICAL UNIVERSITY M. PHARM. - SEMESTER - I • EXAMINATION - WINTER 2012

•	Subject code: 910104 Date: 09/01/201		
_		ne: Biological Evaluations and Clinical Research am - 01.30 pm Total Marks:	: 80
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	2. Ma	empt any five questions. ke suitable assumptions wherever necessary. tures to the right indicate full marks.	
Q.1	(a) (b) (c)	Write down the interpretation techniques used for LAL tests. Write a short note on IRMA. What is GCP? Give a brief account on components of GCP guidelines.	06 05 05
Q.2	(a) (b) (c)	Write details of slope-ratio method for bioassay. Comment: ELISA is superior than EMIT. Give the points to take in consideration for NDA.	06 05 05
Q.3	(a) (b) (c)	What are biological samples? Give types and collection methods for biological samples. Write a short note on laboratory automation in bioanalysis. Enumerate the techniques for depyrogenations. Explain any two techniques in details.	06 05 05
Q.4	(a) (b) (c)	Give the significance of microbial limit test. Give methods used for microbial limit test. What is drug development? Give different stages of drug development. What is pharmacokinetic study? Give its importance.	06 05 05
Q.5	(a) (b) (c)	Enlist the guidelines for bioequivalence study. Explain in brief any one in detail. Write a short note on Genotoxicity Write a short note on Helsinki declaration.	06 05 05
Q. 6	(a) (b) (c)	Give the importance of drug regulation. Give the brief account on guidelines used to conduct clinical trials. In comparison to mammilary model, the caternay model is less useful, Explain.	06 05 05
Q.7		Write short note on any three (i) Protein precipitation method (ii) Single dose fasting two-way crossover bioequivalence study. (iii) Antimicrobial preservative effectiveness testing (iv) Phase III clinical trials	16
