

GUJARAT TECHNOLOGICAL UNIVERSITY
M. PHARM. - SEMESTER – I • EXAMINATION – WINTER 2012

Subject code: 910104**Date: 09/01/2013****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.

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| Q.1 | (a) Write down the interpretation techniques used for LAL tests. | 06 |
| | (b) Write a short note on IRMA. | 05 |
| | (c) What is GCP? Give a brief account on components of GCP guidelines. | 05 |
| Q.2 | (a) Write details of slope-ratio method for bioassay. | 06 |
| | (b) Comment: ELISA is superior than EMIT. | 05 |
| | (c) Give the points to take in consideration for NDA. | 05 |
| Q.3 | (a) What are biological samples? Give types and collection methods for biological samples. | 06 |
| | (b) Write a short note on laboratory automation in bioanalysis. | 05 |
| | (c) Enumerate the techniques for depyrogenations. Explain any two techniques in details. | 05 |
| Q.4 | (a) Give the significance of microbial limit test. Give methods used for microbial limit test. | 06 |
| | (b) What is drug development? Give different stages of drug development. | 05 |
| | (c) What is pharmacokinetic study? Give its importance. | 05 |
| Q.5 | (a) Enlist the guidelines for bioequivalence study. Explain in brief any one in detail. | 06 |
| | (b) Write a short note on Genotoxicity | 05 |
| | (c) Write a short note on Helsinki declaration. | 05 |
| Q. 6 | (a) Give the importance of drug regulation. | 06 |
| | (b) Give the brief account on guidelines used to conduct clinical trials. | 05 |
| | (c) In comparison to mamillary model, the caternay model is less useful, Explain. | 05 |
| Q.7 | Write short note on any three | 16 |
| | (i) Protein precipitation method | |
| | (ii) Single dose fasting two-way crossover bioequivalence study. | |
| | (iii)Antimicrobial preservative effectiveness testing | |
| | (iv) Phase III clinical trials | |