

GUJARAT TECHNOLOGICAL UNIVERSITY**M.PHARM- SEM-I-EXAMINATION – JULY 2012****Subject code: 910104****Date: 05/07/2012****Subject Name: Biological evaluation and Clinical Research****Time: 02:30 pm – 05:30 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) | What are pyrogens? Describe the chemistry and biological effects of pyrogens. | 06 |
| | (b) | Describe the principle of LAL test. Give its advantages and disadvantages. | 05 |
| | (c) | Describe Gel-Clot technique for LAL test. | 05 |
| Q.2 | (a) | Describe membrane filtration method for sterility test. | 06 |
| | (b) | What is sterility test? Give its principle, objectives and limitations. | 05 |
| | (c) | Describe direct inoculation method for sterility testing for aqueous and nonaqueous solutions. | 05 |
| Q.3 | (a) | What is bioassay? Give its principle. Describe slope-ratio model of bioassay. | 06 |
| | (b) | Describe methods used for the evaluation of bioassay. | 05 |
| | (c) | Describe radio-immuno assay of insulin. | 05 |
| Q.4 | (a) | What is toxicity study? Describe briefly the parameters for measuring toxic effect. | 06 |
| | (b) | Discuss acute toxicity. | 05 |
| | (c) | Explain LD ₅₀ and ED ₅₀ . Describe method for their determination. | 05 |
| Q.5 | (a) | Describe objectives and study design of clinical trials. | 06 |
| | (b) | Discuss clinical trial protocol. | 05 |
| | (c) | Describe briefly Good clinical practices. | 05 |
| Q. 6 | (a) | Explain: Pharmacokinetic, bioavailability and bioequivalence. How the BA and BE is assessed? | 06 |
| | (b) | Give importance of bioequivalence study. Describe briefly design and conduct of bioequivalence. | 05 |
| | (c) | Describe one compartment open model- intravenous infusion | 05 |
| Q.7 | | Write short notes on the following: | 16 |
| | a. | Extraction of drugs from biological matrix | |
| | b. | Microbial limit test | |
| | c. | Depyrogenation | |
