

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharmacy Sem-I Examination January 2010

Subject code: 910104

Subject Name: Biological Evaluations and Clinical Research

Date: 23 / 01 / 2010

Time: 12.00 – 3.00 pm

Instructions:

Total Marks: 80

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) Describe the LAL test for pyrogens. | 06 |
| | (b) Describe depyrogenation techniques in detail. | 05 |
| | (c) Discuss acute toxicity. | 05 |
| Q.2 | (a) Describe principle of GCP as per ICH guideline. | 06 |
| | (b) Describe investigator brochure. | 05 |
| | (c) Explain: Investigator, Sponsor, Informed consent, protocol and serious adverse effects. | 05 |
| Q.3 | (a) What is biological standardization? Give its importance. Describe parallel–line model of bioassay. | 06 |
| | (b) Describe matching and graphical method of bioassay. | 05 |
| | (c) What is radio immunoassay? Describe its principle. Give its advantages and limitations. | 05 |
| Q.4 | (a) Explain: Pharmacokinetic, bioavailability, bioequivalence and steady state. | 06 |
| | (b) Describe advantages of urinary excretion studies. Explain also the criteria for obtaining valid urinary excretion data. | 05 |
| | (c) Describe briefly design and conduct of bioequivalence. | 05 |
| Q.5 | (a) What is toxicity study? Describe briefly the parameters for measuring toxic effect. | 06 |
| | (b) Describe toxicity testing of plastic container for ophthalmic preparations. | 05 |
| | (c) Why is test for bacteriostasis and fungistasis carried out before sterility testing. Describe method A of sterility testing. | 05 |
| Q. 6 | (a) Describe one compartment open model- intravenous infusion. | 06 |
| | (b) Explain, classify and give uses of pharmacokinetic models. | 05 |
| | (c) Describe microbial limit tests with its applications. | 05 |
| Q.7 | Write a short notes on the followings:
a. Bio-waver
b. Rabbit pyrogen test
c. Extraction of drugs from biological matrix. | 16 |
