

GUJARAT TECHNOLOGICAL UNIVERSITY
M. Pharm. – SEMESTER – I • EXAMINATION – SUMMER • 2014

Subject Code: 910104**Date: 23-05-2014****Subject Name: Biological Evaluations 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) Explain: Acute toxicity, chronic toxicity and mutagenicity. | 06 |
| | (b) Describe the parameters for measuring toxic effect. | 05 |
| | (c) Describe toxicity testing for plastic container. | 05 |
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| Q.2 | (a) Describe objectives and design of clinical research protocol. | 06 |
| | (b) What is Helsinki declaration? Describe its content. | 05 |
| | (c) Explain the methods for determination of bioavailability. | 05 |
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| Q.3 | (a) What is sterility testing? Explain the membrane filtration method for sterility testing. | 07 |
| | (b) What is pyrogen? Give suitable classification of it. Discuss rabbit pyrogen test with its advantages and limitations. | 09 |
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| Q.4 | (a) What is bioassay? Discuss their scope, advantages and limitations over other assay methods. | 09 |
| | (b) What are preservatives? Describe the test carried out for determining the effectiveness of an antimicrobial preservative. | 07 |
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| Q.5 | (a) What are pharmacokinetic models? Classify them. Discuss merits and demerits of compartment modeling. | 09 |
| | (b) Describe one compartment open model for intravenous infusion. | 07 |
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| Q. 6 | (a) Discuss the selection of biological sample and various extraction methods for the extraction of drug from biological sample. | 08 |
| | (b) Discuss the responsibility of the independent ethics committee. | 08 |
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| Q.7 | Write short-notes on the following | 16 |
| | (a) Radio immunoassay (b) GCP (c) LAL Test | |
| | (d) Graphical method of bioassay | |
