

GUJARAT TECHNOLOGICAL UNIVERSITY**M. Pharm. SEMESTER – I . EXAMINATION- SUMMER --2016****Subject Code:910104****Date: 27/05/2016****Subject Name: Biological Evaluations and Clinical Research.****Time: 10:30 AM to 1:30 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) | Give detail note on bioassay of Oxytoxin or d-tubocurarin | 06 |
| | (b) | Describe matching and graphical method of bioassay. | 05 |
| | (c) | Describe direct inoculation method for sterility testing for aqueous and non-aqueous solutions. | 05 |
| Q.2 | (a) | Write a detail note on Depyrogenation | 06 |
| | (b) | Discuss about the LAL test for pyrogens | 05 |
| | (c) | Describe the source, chemistry, properties and usual limits of endotoxins in pharmaceutical products. | 05 |
| Q.3 | (a) | Define: AUC, C_{max} , t_{max} , pharmaceutical equivalent, absolute bioavailability | 06 |
| | (b) | Explain radioimmunoassay of Insulin. | 05 |
| | (c) | Write a note on protein precipitation method. | 05 |
| Q.4 | (a) | What is Radio immunoassay? Describe its principle and mention its advantages and disadvantages. | 06 |
| | (b) | Explain mutagenicity, teratogenicity and sub acute toxicity in details. | 05 |
| | (c) | Describe membrane filtration method for sterility test | 05 |
| Q.5 | (a) | Discuss detail about Good clinical practice. | 06 |
| | (b) | Define Toxicity. Enlist the parameters for measuring the toxic effect and describe any three in detail. | 05 |
| | (c) | Describe objectives and study design for clinical trials. | 05 |
| Q. 6 | (a) | Describe one component open model for intravenous infusion. | 06 |
| | (b) | Describe briefly design and conduct of bioequivalence study. | 05 |
| | (c) | Write a note on interpretation of sterility testing. | 05 |
| Q.7 | (a) | Describe Helsinki declaration of clinical trial. | 06 |
| | (b) | Describe toxicity testing of plastic container for ophthalmic preparation. | 05 |
| | (c) | Write a note on extraction of drugs from biological matrix. | 05 |
