

Seat No.: \_\_\_\_\_

Enrolment No. \_\_\_\_\_

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**M. Pharm. – SEMESTER I – EXAMINATION – SUMMER -2018**

**Subject Code: 910104****Date: 05/05/2018****Subject Name: BIOLOGICAL EVALUATIONS AND CLINICAL RESEARCH****Time: 02:30PM TO 05:30PM****Total Marks: 80****Instructions:**

1. Attempt any five questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

- Q.1** (a) Define Bioassay. Explain different types of Bioassay. **06**  
(b) Explain bioassay of Insulin. **05**  
(c) What are Pyrogens? Describe the chemistry and biological effects of pyrogens **05**
- Q.2** (a) What are biological fluids? Explain method of collection of different biological fluids. **06**  
(b) Write a note on LLE. **05**  
(c) Write note on Pyrogen testing or LAL test. **05**
- Q.3** (a) Explain in detail different concepts of pharmaceutical Equivalents. How bioavailability can be measured? **06**  
(b) Explain the regulatory aspects of bioavailability. **05**  
(c) Explain Helsinki declaration. **05**
- Q.4** (a) Write a note on roles and responsibilities of IRB/IEC. **06**  
(b) Write a note on GCP. **05**  
(c) Write a note on clinical trial protocol. **05**
- Q.5** (a) What is Pharmacokinetic? Explain in detail about Cmax and AUC. **06**  
(b) Explain various pharmacokinetic models. **05**  
(c) What are the applications of Pharmacokinetics? **05**
- Q. 6** (a) Explain test for effectiveness of antimicrobial preservatives. **06**  
(b) Explain toxicity. Explain various parameters for toxicity testing. **05**  
(c) Explain the sterility testing and microbial limit test in detail. **05**
- Q.7** (a) Explain the sterility testing of following: **06**  
1) Catgut 2) oily injections 3) Atmospheric air.  
(b) Write a note on IRMA. **05**  
(c) Describe objective and study design of clinical trial. **05**

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