

# UKA TARSADIA UNIVERSITY

M.Pharm. (QA) (1st Semester)

040030102 - Biological Evaluations and Clinical Research

Time : 10:00 am to 1:00 pm

Date : 23/12/2013

Duration: 3 Hours

Max. Marks: 70

**Instructions:**

1. Attempt all questions.
2. Write each section in a separate answer book.
3. Make suitable assumptions wherever necessary.
4. Figures to the right indicate full marks allocated to that question.

## Section 1

- Q.1 Answer briefly**
- a List the techniques available for analysis in biological fluids. Write principle of LLE. **3**
- OR
- a Describe the procedure for bioassay of insulin. **3**
- b Which organisms and growth media are used in microbial limit test? **4**
- c Why are positive and negative controls required in sterility test? **4**
- Q.2 Answer the following (Any 2)** **12**
- a What are immunoassays? Differentiate between RIA and ELISA.
- b Differentiate between endotoxins and exotoxins. Describe Sham test.
- c Discuss the problems associated with analysis of drug in biological samples.
- Q.3 Answer the following (Any 2)** **12**
- a Explain the different general methods for bioassay.
- b Describe the different endpoint determination techniques in LAL test.
- c Write a note on IP method of sterility testing.

## Section 2

- Q.4 Answer briefly**
- a Explain the terms bioavailability and bioequivalence. **3**
- OR
- a Explain the term pharmacokinetics. Write its significance. **3**
- b Describe the methods for measurement of absorption rate. **4**
- c What do teratogenicity and mutagenicity studies involve? **4**
- Q.5 Answer the following** **12**
- a Discuss the underlying principles of GCP guidelines.
- OR
- a Discuss the importance of the Helsinki declaration.
- b Write the content of a clinical research protocol.
- OR
- b Write the content of Investigator's Brochure.
- Q.6 Answer the following (Any 2)** **12**
- a Discuss the importance of preclinical drug evaluation. How is a drug evaluated for its biological activity?
- b Describe the different pharmacokinetic models giving significance of each.
- c Discuss the functions of the Review Board as per GCP guidelines.

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