

UKA TARSADIA UNIVERSITY

Maliba Pharmacy College

M. Pharm. Quality Assurance 1st Semester Internal Examination December 2013**040030102 Biological Evaluations & Clinical Research**

Time: 10:30 a.m. To 1:30 p.m.

Max. Marks: 70

Date: 06/12/2013

Instructions:

- Attempt all questions.
- Figures to the right indicate full marks.

SECTION 1

- Q.1. Answer in brief:** **11**
- a What are pyrogens? Discuss their properties. **3**
- OR
- a Write the importance of negative and positive controls in sterility test. **3**
- b Describe the Sham test for pyrogens. **4**
- c Discuss the interpretation of sterility test. **4**
- Q.2. Answer the following:** **12**
- a Explain the principle of radio immunoassay. Give the applications of RIA. **6**
- OR
- a Explain the principle of solid phase extraction technique. Write its advantages. **6**
- b Write the general principle of bioassay. Discuss the advantages and limitations of bioassays. **6**
- OR
- b Describe the different methods of bioassay. Explain any one in detail. **6**
- Q.3. Answer in detail: (Any 2)** **12**
- a Why is analysis of drugs in biological fluids difficult? Discuss different pretreatment methods. **6**
- b Write a note on determination of effectiveness of antimicrobial preservatives. **6**
- c Describe the pharmacopoeial procedure for microbial limit test. **6**
- SECTION 2**
- Q.4. Answer in brief:** **11**
- a Why are toxicity studies required? What are teratogenicity and mutagenicity studies? **3**
- OR
- a What are LD₅₀ and ED₅₀? **3**
- b How are acute, sub-acute and chronic toxicity studies performed? **4**
- c Describe the different phases of clinical trials. **4**
- Q.5. Answer the following:** **12**
- a Discuss the important principles on which ICH E6 guidelines are based. **6**
- OR
- a Discuss the composition and duties of institutional review board. **6**
- b Explain the different methods of determining bioavailability. **6**
- OR
- b Write the importance of bioavailability determination. Discuss its applications. **6**
- Q.6. Answer in detail: (Any 2)** **12**
- a What is a clinical research protocol? Describe its content. **6**
- b Describe the different models to study pharmacokinetics. **6**
- c Discuss the applications of pharmacokinetics in development of new drug and dosage form. **6**