Maliba Pharmacy College

M.Pharm. (Quality Assurance)

Semester 1

(040030102) Biological Evaluations and Clinical Research

Time : 3 hours / Max. marks : 70

Instructions:

1. Attempt all questions.

2. Write each section in a separate answer book.

Section-I

Q-1 **Answer in brief: (Any 5)** **[05]**

a. Write full form of ELISA.
b. What does LAL stand for?
c. What are pyrogens?
d. Why are preservatives added to formulations?
e. What is Sham test?
f. Write the principle behind sterility testing.

Q-2 **Answer the following in brief: (Any 5)** **[10]**

a. What are the negative controls used in sterility testing? Why are they required?
b. Discuss the advantages of bioassays over chemical methods.
c. Describe the chemical nature of endotoxins.
d. Write the principle behind RIA.
e. Discuss the problems associated with analysis of drugs from biological fluids.
f. What is MVD in LAL test?

Q-3 **Answer the following: (Any 4)** **[20]**

a. Describe any one method for sterility testing.
b. Explain the liquid-liquid extraction method for separation of drugs from biological fluids.
c. Describe briefly the significance of microbial limit test and interpretation of results in MLT.
d. Write a note on the LAL test.
e. Describe with examples the various types of bioassay methods.

Section-2

Q-4 **Answer in brief: (Any 5)** **[05]**

a. Define bioavailability.
b. Define pharmacokinetics.
c. What does ICH stand for?
d. What are LD50 and ED50?
e. Enlist the various types of toxicity studies.
f. What is a biowaiver?

Q-5 **Answer the following : (Any 5)** **[10]**

a. Describe the different phases of clinical trials.
b. What is Helsinki declaration?
c. Define C_{max} and T_{max}.
d. What is bioequivalence study? Give its significance.
e. What are mutagenicity studies?
f. What is passive diffusion?

Q-6 Answer the following: (Any 4) [20]

a. Explain the responsibilities of the IRB during clinical trial.
b. What is a clinical research protocol? Describe its content.
c. Describe the methods to measure bioavailability.
d. Explain briefly the different pharmacokinetic models.
e. Write the significance of preclinical toxicity studies. Explain the parameters measured to determine toxicity.
