UKA TARSADIA UNIVERSITY

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

Subject :040030102 **-** Biological Evaluations and Clinical Research

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.
5. Draw diagrams/figures whenever necessary.

Section-1

Q-1 (A) Answer the following. **[07]**

I) What are the limitations associated with bioassays?
II) What are endotoxins?
III) Name the three methods used for microbial limit test.
IV) What should be done when the preparation to be tested for sterility is bacteriostatic?
V) What is meant by quantal response in bioassay?
VI) Why is pretreatment of biological sample required before analysis?
VII) Write the full form of LAL test.

Q-1 (B) Answer the following in brief. (Any 4) **[08]**

I) Name the growth media used for detection of aerobes and anaerobes in sterility testing.
II) What is 'test for bacteriostasis/fungistasis'?
III) Write the different radiolabelling techniques.
IV) Enlist the applications of RIA.
V) Explain the principle behind sterility test.
VI) Write the principle behind liquid-liquid extraction.

Q-2 Answer the following. **[10]**

A) What are immunoassays? Explain the principle behind RIA.

OR

A) Write a note on the procedure and interpretation of Sham test.
B) What controls are required during sterility testing? How will you interpret the results?

OR

B) Describe the membrane filtration method for sterility testing. Give its advantages.

Q-3 Answer the following in detail. (Any 2) **[10]**

A) Explain the IP method for determining the effectiveness of antimicrobial preservatives.
B) Discuss the different statistical models used in bioassays.
C) Write a note on LAL test.

Section-2

Q-4 (A) Answer the following. **[07]**

I) What are bioequivalence studies?
II) What is the aim of toxicity testing?
III) What is the goal of ICH?
IV) What are pharmaceutical equivalents?
V) Mention the objective of bioavailability studies
VI) What are carcinogenicity and mutagenicity studies?
VII) What is the objective of GCP guideline?

Q-4 (B) Answer the following in brief. (Any 4) **[08]**

I) Write a brief note on blood brain barrier.

II) What are the rate-limiting steps in hepatic clearance of drugs?

III) Explain characteristics of passive diffusion.

IV) Name the different documents and records prepared during clinical trials.

V) What is a bioequivalence study? Write its scope.

VI) What is Helsinki declaration?

Q-5 Answer the following. **[10]**

A) Discuss the responsibilities of sponsor of clinical trial.

OR

A) Describe the acute and sub-acute toxicity testing for new drugs.

B) Explain how bioavailability is determined?

OR

B) Discuss relative merits and demerits of models as they are applied to pharmacokinetic studies.

Q-6 Answer the following in detail. (Any 2) **[10]**

A) Write the role of Ethics Committee during clinical trial.

B) Describe the content of investigator brochure. What is the brochure used for?

C) Give a detailed account of the parameters for measuring toxic effects.