UKA TARSADIA UNIVERSITY

Masters in Pharmacy (Quality Assurance)

Semester 1 – January 2012

Subject Code: 040030102 Biological Evaluations and Clinical Research

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.
5. Draw diagrams/figures whenever necessary.

Section-I

Q-1 (A) Do as directed: **[07]**

I) What does LAL stand for?
II) What is meant by RIA?
III) What are bacteriostasis and fungistasis tests?
IV) What are antimicrobial preservatives?
V) What are pyrogens?
VI) Name the different growth media used in sterility testing.
VII) Name the specific pathogens tested for as part of microbial limit test.

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

I) What is bioassay? Give its advantages and limitations.
II) Explain briefly the principle behind ELISA.
III) What is MVD in LAL test?
IV) Enlist the various radiolabelling techniques for RIA.
V) Enumerate the pretreatment methods for analysis of drugs in biological samples.
VI) What is the significance of positive and negative controls used in sterility testing?

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

A) What is sterility testing? Describe membrane filtration method giving its advantages and limitations.

OR

A) Discuss the significance of and procedure for microbial limit test.
B) Explain solid phase extraction method for extraction of drug from biological samples.

OR

B) Explain liquid-liquid extraction method for extraction of drug from biological samples.

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

A) Describe the parallel-line and slope-ratio models for bioassay.

B) Describe the test for effectiveness of antimicrobial preservatives.

C) Compare the rabbit test with LAL test.

Section-2

Q-4 (A) Do as directed: **[07]**

I) What is meant by GCP?
II) What is preclinical toxicity testing?
III) What is LD50 and ED50?
IV) What is pharmaceutical equivalence?
V) What is teratogenicity study?
VI) What is meant by the term metabolism?
VII) Enlist the various types of toxicity studies.

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

I) Explain the significance of chronic toxicity testing.
II) What is Helsinki declaration?
III) Name the various pharmacokinetic models.
IV) What is bioequivalence? Give its significance.
V) Explain the various phases of clinical trials.
VI) What are biowaivers?

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

A) Explain the responsibilities of the sponsor of a clinical study.

OR

A) What is a clinical research protocol? Describe its content.

B) What are acute and sub-acute toxicity studies? How are they performed?

OR

B) What are the objectives of bioavailability study? Explain the parameters determined in the plasma level-time study for bioavailability measurement.

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

A) Discuss the applications of pharmacokinetic study in new drug discovery and development.
B) Describe the content of the investigator's brochure.
C) What are the duties and responsibilities of the Independent Ethics Committee?

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