

M.Sc. Course in Clinical Research
Semester II Examination, 2023
Paper Code: MCR DCC 202
ADVANCED CLINICAL RESEARCH

Time: 2.5 hours

Maximum Marks: 60

Attempt All questions. All parts of a question must be attempted in continuation. Start answer of a fresh question on a new page. Cite examples and draw diagrams whenever necessary.

Question 1. Write briefly on the importance of the following:

[4x3=12]

- a. Lead optimisation.
- b. Spontaneously hypertensive rats.
- c. Enteric coated tablets.
- d. Ethic in use of placebo.

Question 2.

[12 marks]

Write in detail regarding the preferred sources of NCEs entering the drug discovery process in the 21st century.

OR

Discuss in detail the factors that guide the selection of animal species in pre-clinical drug development keeping in mind the extrapolation to humans.

Question 3.

[12 marks]

Write with adequate examples the advantages and disadvantages of (a) subcutaneous injections of insulin in a diabetic patient (b) nanoparticle formulation.

OR

Discuss BCS classification of drug molecules. Discuss the influence of this classification on development and clinical data requirement of new formulations (generic and non-generic).

Question 4.

[12 marks]

Discuss the importance of bioassays in an age when state-of-the-art facilities for liquid chromatography are available.

OR

Eprosartan was administered to male and female rats orally by gavage for 28 days at dose levels of 0, 30, 100, 1000 mg/kg/day. Mortality and clinical signs of toxicity was observed in one male in the 30 mg/kg/day dose group died prior to dosing on day 18. No deaths occurred at the two higher doses. Identify the NOAEL. Considering the rat-to-human conversion factor is 0.08 and dog-to-human conversion factor as 0.541, describe the step-by-step approach to calculate the Maximum Recommended Starting Dose (MRSD) in 60 kg man using safety factor of 1/10.

Question 5.

[12 marks]

Compare the objectives and design of Phase I clinical trial of a cytotoxic compound?

OR

Discuss the characteristics of matching placebo and placebo response.