

M.Sc. Course in Clinical Research
Semester II Examination, 2024
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. Lipinski's rule of 5.
- b. Three-point bioassay.
- c. Advantages and disadvantages of sublingual drug administration.
- d. Double Dummy technique.

Question 2. Write briefly on any THREE of the following:

[4x3=12]

- a. Target product profile.
- b. High throughput screening.
- c. Combinatorial chemistry.
- d. Hit-to-Lead.
- e. Lead optimisation.

Question 3.

[12 marks]

Fenofibrate 200 mg capsules are used to treat raised serum triglycerides and cholesterol. A new micronized 145 mg tablet of the drug has been developed. What data will be required to demonstrate clinical equivalence?

OR

Retention enema of hydrocortisone is sometimes used to treat ulcerative colitis. What are the different types of enemas? Discuss the uses, advantages and disadvantages of enemas.

Question 4.

[12 marks]

Write briefly on (a) Dose range finding studies (b) male reproductive toxicity study (c) Ocular Toxicity studies.

OR

Write briefly animal models used to identify NCEs with (a) anti-hypertensive activity (b) anticancer activity and (c) analgesic activity.

Question 5.

[12 marks]

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

OR

Discuss the characteristics of Phase III clinical trials of antibacterial agent for AECB (acute exacerbations of chronic bronchitis).