2023

Your Roll Number……

SCHOOL OF CHEMICAL AND LIFE SCIENCES
B.Sc. (Hons.) CLINICAL RESEARCH
SEMESTER-I, EXAMINATIONFeb-2024

PAPERCODE: BCR DSC101

PAPERTITLE: INTRODUCTION TO CLINICAL RESEARCH

Time: 2.5Hrs **Maximum Marks: 60**

Write the roll number at the top immediately on receipt of this question paper. 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 whenever necessary

Q 1. Define the following [2x6]

i) Belmont report
ii) Cross-over study design
iii) Bioavailability
iv) Power of the clnical study
v) Assent form
vi) Equivalence trials

Q2. Discuss various component of informed consent form. [12]

OR

Discuss drug development process in detail.

Q 3. Discuss in detail the constitution, function, and responsibilities of IEC [12]

OR

What is TMF and discuss its various component.

Q 4.Define bias. Discuss various sources and methods to control bias [12]

OR

Write a short note various historical event that formed the basis of the guidelines.

Q5. Discuss endpoints in the clinical trials. [12]

OR

Explain in detail Phase 0 clinical trial.