Your Roll Number.....

SCHOOL OF CHEMICAL AND LIFE SCIENCES

B.Sc. Hons in Clinical Research

SEMESTER-IV, EXAMINATION July-2024

PAPER CODE: BCR DSC- 402

PAPER TITLE: Regulatory Aspects in Clinical Trials

Time: 2.5 Hrs. **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 answering a fresh question on a new page. Cite examples whenever necessary

Q 1. Short Answers [1.5 * 10=15]

a. Define CTD.
b. Write the full form of PASS and PAES.
c. Write the full form of NICE.
d. Write the full form of OECD.
e. Define IND.
f. Define market authorization.
g. Define spontaneous reporting.
h. Define safety report filing.
i. Who is the current DCGI?
j. What is post-marketing surveillance?

Q2. Write a short note on **ANY THREE** from the following [5*3=15]

a. Pure Food and Drugs Act
b. Regulation of BA/BE studies
c. Hatch Waxman Act
d. Nuremberg Code
e. Regulation of Medical Devices

Q 3. Describe any **ANY TWO** questions from the following [15 * 2= 30]

a. Abbreviated New Drug Application
b. Good Laboratory Practices
c. Declaration of Helsinki
d. Common Technical Document