2022

SCHOOL OF CHEMICAL AND LIFE SCIENCES
B.Sc. Hons. Clinical Research Semester II Examination October-2023
PAPERCODE: BCR DSC 201
PAPER TITLE: Drug Discovery and Development

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 answer of afresh question on a new page. Cite examples whenever necessary.

Q1 Define the following (1.5x10=15)

a. Proof of concept in drug development
b. Maximum tolerated dose
c. Therapeutic index
d. Biopharmaceutical classification system (BCS)
e. Double blind method
f. New Chemical Entity
g. Placebo
h. IND
i. NDA
j. Quality assurance

Q2. Attempt **ANY THREE** questions from the following (5x3=15)

a. Helsinki declaration
b. Mutagenicity
c. Master formula record
d. High throughput screening.
e. Role of transgenic animals in target validation.

Q3. Describe the key stages of drug development, from discovery to market approval. (15)

OR

Discuss in detail the various phases of clinical trial. How does preclinical testing in drug development differ from clinical trial

Q4. What are different types of drug formulations? Explain in details about in process quality control and finished product quality control of tablets and capsules. (15)

OR

Describe the fundamental principles of Good Manufacturing Practices and their significance in ensuring the quality and safety of pharmaceutical products.