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School of Pharmaceutical Education and Research
M. Pharm. I Semester Examination (2023-24)

Your Roll No.

Subject: **Clinical Research**
 Paper Code: **MPP 104 T**

Date: **15-03-2024**

Maximum Marks: **75**
 Time: **Three hours**

(Write your Roll No. on the top immediately on receipt of this question paper)

Note: This paper has two Sections; A and B.

Attempt all the two sections.

Section A: Answer all the questions.

Section B: Answer any 4 out of 6 questions

Abbreviations Used:

CO- Course Outcome, PO- Program Outcome, BTL- Bloom Taxonomy Level: BT level 1- Remember; BT level 2- Understand; BT level 3- Apply; BT level 4- Analyze; BT level 5- Evaluate; BT level 6- Create.

SECTION-A

Answer the following in brief (Attempt all questions)

5x3= 15 Marks

Q. No 1	Question	BTL	CO	PO
(a)	Therapeutic equivalence	2	2	2
(b)	Cross sectional study	3	2	2
(c)	IRB	2	2	3
(d)	ICF	2	3	2
(e)	Data archiving	2	4	3

SECTION B

Long type Questions (Attempt any 4 out of 6)

4x15= 60 Marks

	Question	BTL	CO	PO
Q. No 2	What are the roles and responsibilities of ethics committee? Write its composition.	3	2	2
Q. No 3	What is randomization process and discuss different techniques of Randomization?	2	3	3
Q. No 4	What are BA/BE studies? Discuss different methods for Bioavailability assessment and also discuss in vitro BA/BE studies?	4	4	3
Q. No 5	Discuss the role and responsibilities of PI in Clinical Trials?	2	2	3
Q. No 6	Discuss data management Plan? Also discuss data mining and archiving?	2	2	3
Q. No 7	Discuss in detail the clinical trial start-up activities and challenges faced during the process	4,5	3,2	2