INDIRA UNIVERSITY, PUNE

SCHOOL OF PHARMACY- MPHARM (Pharmacology)

Term End Examination (2025 Pattern) April- May – 2026- Semester – II

Course Name: Clinical Research and Pharmacovigilance **Max. Marks: 75**
Course Code: MPL204T **Time: 3:00 Hrs.**

Instructions

- All Questions are Compulsory. Write two sections on separate answersheets.
- Neat diagram must be drawn wherever necessary.
- Figures to the right indicate full marks.

Section : I

Q.1 Solve any ONE from the following **15 Marks**

a. Explain in detail roles & responsibilities of IRB.

b. Explain in detail the roles and responsibilities of the Investigator.

Q.2 Solve any FOUR from the following **20 Marks**

a. Discuss roles & responsibilities of CRC.

b. Discuss the elements of Informed Consent form.

c. Define ICH. Explain principles of ICH-GCP.

d. Discuss role of ICMR in clinical trial study.

e. Explain in detail Cohort study.

f. Discuss RCT & non-RCT.

Section : II

Q.3 Solve any ONE from the following **15 Marks**

a. Explain in detail the preparation and components of a clinical trial protocol and its significance in research.

b. Elaborate on severity, seriousness, predictability, and preventability assessment of ADRs with examples.

Q.4 Solve any TWO from the following **15 Marks**

a. Discuss Case-control study.

b. Elaborate in detail Clinical study Report.

c. Explain statistical methods used in pharmacovigilance.

d. Explain Targeted Clinical Investigation.

Q.5 Solve any TWO from the following **10 Marks**

a. Elaborate on Safety monitoring in Clinical trial.

b. Discuss causality assessment scale.

c. Discuss International Non-proprietary

d. Explain Pharmacoepidemiology.

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