Examination: Master in Pharmacy First Year Second Semester EXAM 2025
Subject: CLINICAL RESEARCH AND PHARMACOVIGILANCE
Ref. No.: **Ex/MPL204T/2025**
Time: 03 hrs Full Marks: 75

GROUP – A (25 marks)

Q1) Explain the following terms of Pharmacovigilance a) Absolute risk; b) Adverse Event (AE); c) Adverse (Drug) Reaction (ADR); d) Attributable risk (4X4 = 16)

Q2) Discuss about Timeline for reporting an ADR and Objectives of Indian Pharmacovigilance. (4+5=9)

GROUP – B (25 marks)

Q3) Define necrosis. Differentiate between necrosis and Apoptosis. Describe in short about different types of necrosis. (10)

Q4) Write notes in (***any two***) (7.5X2=15)

a) Pharmacovigilance in India.

b) Adverse drug reaction.

c) Clinical trials.

GROUP – C (25 marks)

Answer any one

Q5) Explain the significance of informed consent in clinical evaluation of investigational drugs. Briefly mention the objectives of different phases of clinical trials. (25)

Or

Q6) Discuss the salient features of Declaration of Helsinki with specific reference to clinical trials of investigational drugs. (25)