

Ref. No.: **Ex/MPL204T/2024**

Examination: Master in Pharmacy First Year Second Semester EXAM 2024

Subject: CLINICAL RESEARCH AND PHARMACOVIGILANCE

Time: 03 hrs

Full Marks: 75

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**GROUP – A (25 marks)**

- Q1)** a) Explain about the Thalidomide Tragedy. (04)  
b) Discuss about the necessity for conduct of Pharmacovigilance with some examples. (08)
- Q2)** a) Define the term Pharmacovigilance, AE and ADR. (3x2)  
b) What do you mean by Spontaneous Reporting and Mandatory Reporting? (2x3)

**GROUP – B (25 marks)**

- Q3)** Define Pharmacovigilance. Write down the main objectives of Pharmacovigilance. Write down the history of Pharmacovigilance in India. (15)
- Q4)** Write down the different phases of clinical trial. (10)

**GROUP – C (25 marks)**

Answer any one

- Q5)** Explain the significance of informed consent in clinical evaluation of investigational drugs. (25)

**Or**

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