PAPER ID-411228

Subject Code: MPL204T

Roll No: | | | | | | | | | | | | | |

MPHARM

(SEM II) THEORY EXAMINATION 2023-24

CLINICAL RESEARCH & PHARMACOVIGILANCE

TIME: 3 HRS **M.MARKS: 75**

Note: 1. Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt *all* questions in brief. **10 x 2 = 20**

a.	Define CRF.
b.	Discuss the thalidomide tragedy.
c.	What do you understand by AEFI?
d.	Write the purpose of ICH-GCP guidelines.
e.	What is ICSR and PSUR?
f.	Define the term "Pharmacoepidemiology".
g.	Explain the term "Odds Ratio".
h.	Discuss the informed consent process.
i.	Distinguish between prospective cohort and retrospective cohort studies.
j.	Mention the features of cross-sectional study.

SECTION B

2. Attempt any *two* parts of the following: **2 x 10 = 20**

a.	Categorize different types of ADRs. Discuss its management.
b.	Elaborate on various methods of active surveillance.
c.	Explain the roles and responsibilities of Sponsor.

SECTION C

3. Attempt any *five* parts of the following: **5 x 7 = 35**

a.	Explain safety monitoring in clinical trials.
b.	Elaborate on vaccine safety surveillance.
c.	Discuss the working of Pharmacovigilance programme of India.
d.	Write a detailed note on Schedule Y guidelines.
e.	Illustrate the components of Protocol.
f.	Give a detailed note on case-control study highlighting its advantages and disadvantages.
g.	Explain the functions of WHO Programme for International Drug Monitoring.