Subject Code: MPL204T

PAPER ID-421132

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

MPHARM
(SEM II) THEORY EXAMINATION 2021-22
CLINICAL RESEARCH & PHARMACOVIGILANCE

Time: 3 Hours ***Total 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 the term 'Informed consent'.
b.	List the methods for causality assessment of adverse events.
c.	Define the terms 'Relative Risk' and 'Odd's ratio'.
d.	Explain "Pharmacoeconomics".
e.	Differentiate between 'dechallenge' and 'rechallenge'.
f.	Identify the aims and objectives of pharmacovigilance.
g.	Explain cross-sectional study with its merits and demerits.
h.	Recall thalidomide tragedy.
i.	Distinguish between active surveillance and passive surveillance.
j.	Write the contents of Investigator's Brochure.

SECTION B

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

a.	Discuss the role and responsibilities of sponsor.
b.	Illustrate WHO international drug monitoring programme.
c.	Explain the framework of observational studies covering its advantages and disadvantages.

SECTION C

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

a.	Examine various types of adverse drug reactions.
b.	Illustrate the origin and principles of ICH-GCP guidelines.
c.	Write a detailed note on preparation of protocol.
d.	Illustrate "Spontaneous reporting system". Examine its advantages and limitations.
e.	Demonstrate different types of randomized clinical trials.
f.	Explain the working and layout of Pharmacovigilance Programme of India.
g.	Write a detailed note on safety monitoring in clinical trials with emphasis on the role of stakeholders.