22-05-2024

W 021/015

Enrolment Number

Total No. of printed pages = 01

Winter, 2024

M.Pharm 2nd Semester Examination

Clinical Research and Pharmacovigilance

Course Code: MPL204T

Full Marks – 75 **Time – 3 hours**

The figure in the margin indicates full marks for the questions.

I. Answer the following short questions **2 x 10= 20**

1. Explain the responsibilities of a sponsor in a Clinical Trial.
2. Explain significance of safety monitoring.
3. Differentiate between side effect and adverse drug event.
4. Enumerate the principles of pharmacovigilance.
5. Write the composition of EC.
6. Define Clinical Study Report and its basic structure.
7. Write in brief about ICH-GCP.
8. Write the advantages and disadvantages of targeted clinical trial.
9. Write the events leading to formation of ICH.
10. Differentiate between trade name and non-proprietary names.

II. Answer the following short questions (150 words) (*Any seven*) **5 x 7= 35**

1. Explain the principles of cohort study
2. Write in brief the guidelines for Biomedical Research.
3. Write a short note on need of ICD and mention highlights of ICD 11.
4. Define Clinical Trial Protocol. Explain guideline for preparation of protocol for clinical trial.
5. Write in brief note on Schedule Y
6. Write a short note vaccine safety surveillance.
7. Write about the reporting system in ADR.
8. Write a short note on INN in India.
9. Write in brief about Pharmacoeconomics and its importance in clinical research.

III. Answer the following long questions (250-300 words) (*Any two*) **2 x10= 20**

1. Write briefly about ADR detection and reporting methods.
2. Explain the responsibilities, composition, functions of IRB.
3. Elaborate the informed consent process and the personnel involved as per ICMR guidelines
4. Write in detail about the roles and responsibilities of personnel involve in Pharmacovigilance