Total No. of printed pages = 2

MPL204T

23/08/22

Roll No. of candidate | | | | | | | | | | |

2022

M.Pharm. (Pharmacology) 2nd semester End-Term Examination

CLINICAL RESEARCH AND PHARMACOVIGILANCE

Full Marks – 75 Time – Three hours

The figures in the margin indicate full marks for the questions.

1. Answer the following 2 x10= 20

   a. Define the terms: Side effect and Adverse drug event.

   b. Differentiate between trade names and non-proprietary names.

   c. Explain the methods of causality assessment in ADR reporting

   d. Explain the Principles of ICH guidelines for clinical research.

   e. Explain the responsibilities of sponsor as per Schedule Y.

   f. Explain the significance of safety monitoring.

   g. Name the methods used for the assessment of heterogenicity.

   h. What is a cohort study? Explain the advantages and disadvantages of cohort study design.

   i. What is Pharmacovigilance? Explain the principles of Pharmacovigilance.

   j. Write a short note on the WHO international drug monitoring programme.

2. Answer any seven: 5 x7 =35

   a. Describe the guidelines for setting up and running a pharmacovigilance center.

   b. Explain the composition of ethics committee (EC) and criteria for selection of EC members as per Indian Council of Medical Research (ICMR) guidelines.

   c. Explain the responsibilities, composition, function and operation of Institutional review board (IRB).

d. What is Clinical study report? Explain the basic structure and content of clinical study report.

e. What is clinical trial protocol? Explain the guideline for the preparation of protocol for clinical trial.

f. What is Meta-analysis? Explain the steps involved in performing meta-analysis.

g. What is observational study design? Classify the different types of observational study design.

h. What is Targeted clinical investigations? Explain the advantages and disadvantages of it.

i. What is the purpose and uses of ICD. Explain the highlights of ICD 11.

3. Answer any two: 10 x 2=20

a. Explain the aim, selection and process of International Non Propriety Name (INN) for Drugs. Write a note on use of INN in India.

b. Explain the informed consent process as per ICMR guidelines.

c. What is ADR? Explain the types of ADR and write the features and management of each type of ADRs.

d. What is Pharmacoeconomics? Explain the importance of Pharmacoeconomics in clinical research.