

M. PHARM
(SEM-II) THEORY EXAMINATION 2018-19
CLINICAL RESEARCH AND 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. Discuss about origin of GCP guidelines.
 - b. Write a short note on “The Nuremburg Code of 1947”.
 - c. When is it appropriate to use a non-randomized trial design?
 - d. What do you mean by Bias in Case-Control Studies?
 - e. Expand CRF and write its importance in clinical trials.
 - f. What do you mean by Caveat document in Pharmacovigilance?
 - g. Define term “Signal” in Pharmacovigilance.
 - h. Highlight the challenges in vaccine safety surveillance.
 - i. What is the main objective of designing ICD?
 - j. Enlist various statistical methods for evaluating medication safety data.

SECTION B

- 2. Attempt any two parts of the following: 2 x 10 = 20**
- a. Give a detailed account on International Conference on Harmonization-Good Clinical Practice (ICH-GCP) guidelines.
 - b. Discuss the role and responsibility of sponsor and CRO during clinical trial.
 - c. Define the term Pharmacovigilance. Write a note on origin, aim and scope of Pharmacovigilance Programme in India.

SECTION C

- 3. Attempt any five parts of the following: 7 x 5 = 35**
- a. Write in detail about history, objective, functions and review system of ICMR.
 - b. Write a detailed note on Observational research methods. Differentiate Cohort and Case-Control Studies.
 - c. Write a detailed note on “Information Boucher”.
 - d. Write a detailed note on causality assessment of ADRs.
 - e. Explain spontaneous reporting of adverse drug reactions with suitable examples. What are the merits and demerits of spontaneous reporting?
 - f. Give an account on active surveillance and passive surveillance.
 - g. Write a detailed note on targeted clinical investigations.