



DBZ-MPL-204-T

Seat No. _____

M. P. M. (Sem. II) Examination

July - 2022

Clinical Research & Pharmacovigilance : MPL204T

Time : 3 Hours]

[Total Marks : 75

Instruction : Figure to the right indicates full marks.

1 Answer the following questions : **20**

- (A) Enlist different types of ADR.
- (B) Discuss VIGIFLOW in brief.
- (C) Explain Randomized & Controlled Clinical Trial.
- (D) What is blinded study and elaborate its purpose ?
- (E) What are the role of Sponsor in clinical trial ?
- (F) What is CRO ?
- (G) Explain the term COHORT in Cohort Study.
- (H) Make a note on Case control study.
- (I) What is Pharmacovigilance ?
- (J) Mention basic differences between Active and Passive surveillance.

2 Answer the following questions : (ANY TWO) **20**

- (A) Discuss various techniques of Pharmaco-epidemiology.
- (b) Make a detailed note on Pharmacovigilance in India and International aspects.
- (c) Discuss criteria and content of Informed Consent Form.

3 Answer the following questions : (ANY SEVEN)

35

- (A) Discuss Investigator Brochure in depth.
 - (B) Make a note ICH-GCP.
 - (C) Enlist methods of Severity and seriousness assessment. Explain Naranjo causality assessment scale.
 - (D) Discuss National programmes related to pharmacovigilance.
 - (E) Enlist various Pharmacoeconomics Techniques. Explain Cost Minimization Analysis & Cost Benefit Analysis.
 - (F) Discuss ADR Reporting form and its components and example.
 - (G) Explain Vaccine safety surveillance.
 - (H) What is significance of Safety monitoring in Clinical trial ? Elaborate the same in depth.
 - (I) Make a detailed note on tools used in Pharmacovigilance.
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