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PAV-MPL-204-T Seat No. _____

M. Pharm. (Sem. II) Examination

August / September - 2020

MPL-204-T : Clinical Research and Pharmacovigilance

Time : **3** Hours] [Total Marks : **75**

Instruction : Figure to the right indicates full marks for the respective question.

1 Answer the following : **10×2=20**

(1) Give the composition of IRB.

(2) Explain : Pharmacovigllance.

(3) Write the function of CRO in drug discovery.

(4) Define Pharmacoeconomics.

(5) What is Cohort study?

(6) What is double blind randomized clinical trial?

(7) What is the difference between ADR and ADE?

(8) Explain Phase zero clinical trial.

(9) What is TDM?

(10) Explain : active surveillance.

2 Answer the following : (Any **Two**) **2×10=20**

(1) Explain the core principles and advantages of ICH/GCP guidelines. Explain the role of IRB.

(2) Explain the principle of ICMR guideline for human participant and explain in detail the inform consent process.

(3) Explain the types and factors affecting ADR. Describe role of pharmacist in the management of ADR.

3 Answer the following : (Any **Seven**) **7×5=35**

(1) Explain the schedule Y for conducting clinical trial in detail.

(2) Write a note on contract research organization and its management in drug discovery.

(3) Describe the concept of safety pharmacology with reference to drug discovery process.

(4) Explain the roles and responsibility of investigator and sponsor in detail.

(5) Explain the terms randomized control trial and non-randomized control studies with examples.

(6) Explain the flow of drug development process. Discuss the phase-III of the same in detail.

(7) Write a note on Inform consent process.

(8) Write a short note on Investigator Brochure.

(9) Explain the evaluation of medication safety.
