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FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II-Semester (PCI) (Main) Examination,

August 2018

Subject: Clinical Research and Pharmacovigilance

Time: 3 Hrs **Max. Marks: 75**

Note: Answer any five questions. All questions carry equal marks.

1. Define investigator brochure. Discuss abt the contents of IB in clinical trial.

2. a) Explain the principles of ICH-GCP guidelines.
   b) What are the roles and responsibilities of sponsor and contract research organization in clinical trial?

3. Explain in detail abt RCT and NRCT.

4. a) Write in detail abt ethical principles governing informed consent process.
   b) Write abt Schedule Y in clinical trials.

5. Write abt safety monitoring in clinical trial.

6. Give an overview of the regulatory environment in National and International aspects.

7. Write abt predictability and preventability assessment methods of ADR.

8. Write abt
   a) Vigiflow
   b) Aris G of pharmacovigilance.

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