Code No. 13330 / PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II – Semester (PCI) (Main) Examination, August 2019

Subject: Clinical Research & Pharmacovigilance

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

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

1 a) Explain informed consent process.

b) Write the elements of case report form.

2 a) Explain the principles of ICH-GCP Guidelines.

b) What are the composition and responsibilities of IRB?

3 a) Discuss the varis types and design of clinical trials.

b) Explain roles and responsibilities of clinical investigator.

4 Write in detail abt different types of observational studies in clinical trial.

5 Mention the detection and reporting methods of ADR. Write abt management of ADRs.

6 What is pharmacovigilance. Write abt WHO international drug monitoring programme.

7 Define ADR. Write the types of ADR. Explain how it can be monitored.

8 Write abt:
a) Argus
b) Statistical methods for evaluating medication safety data.

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