Code. No: 6120/PCI

FACULTY OF PHARMACY

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

January 2020

Subject : Clinical Research and Pharmacovigilance

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

Note: Answer any Five Questions. All Questions Carry Equal Marks.

1. a) Explain the structure and content of an informed consent process. 8
   b) Describe briefly ICH-GCP guidelines. 7

2. Explain the roles and responsibilities of
   a) Investigator. 7
   b) Contract research organization.

3. Define ADR. Explain the detection and reporting methods of ADRs. 15

4. a) Define pharmacovigilance. Write a note on role of pharmacovigilance in India. 10
   b) Describe briefly abt spontanes reporting system. 5

5. a) Write a note on pharmacoepidemiology. 8
   b) Discuss abt the different types of adverse drug reactions with examples. 7

6. Describe the ICMR guidelines for biomedical research. 15

7. Explain the methods of Safety monitoring in clinical trials 15

8. a) Explain the significance of safety monitoring in clinical trials 7
   b) What are the varis statistical methods for evaluating medication safety data. 8

****