

FACULTY OF PHARMACY

**M. Pharmacy (Pharmacology) II-Semester (PCI) (Supply.) Examination,
January 2020**

Subject : Clinical Research and Pharmacovigilance

Time: 3 Hours

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 about spontaneous reporting system. | 5 |
| 5. a) Write a note on pharmacoepidemiology. | 8 |
| b) Discuss about 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 various statistical methods for evaluating medication safety data. | 8 |

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