Code No. 13174/PCI

FACULTY OF PHARMACY

M. Pharmacy (Pharmacology) II-Semester (PCI) (Suppl.) Examination, February 2019

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 Ethical principles governing informed consent process. (7)
   (b) Describe the schedule Y guidelines for biomedical research (8)

2. (a) Explain Cohort and case studies. (8)
   (b) Define Clinical trials. Explain the different phases of clinical trials. (2+5)

3. (a) Write a note on case report forms. (6)
   (b) What are the varis steps taken to manage adverse d rug reaction. (9)

4. (a) Differentiate the active and passive surveillance of adverse drug reaction. (10)
   (b) Define Pharmacovigilance. What are the roles and responsibilities in Pharmacovigilance. (5)

5. What are the varis guidelines followed for adverse drug reactions reporting. (15)

6. (a) Write a note on safety pharmacology (7)
   (b) What are the varis statistical methods for evaluating medication safety data. (8)

7. (a) Write a note on Pharmacoeconomics. (5)
   (b) Describe briefly abt spontanes reporting system. (5)
   (c) National programmes related to pharmacovigilance. (5)

8. Explain the methods of safety monitoring in clinical trials. (15)

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