QP Code: 825006 **Reg. No……**

Eighth Semester B. Pharm Degree Supplementary Examinations
November 2024
Pharmacovigilance
(2017 Scheme)

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

- ***Answer all questions to the point neatly and legibly • Do not leave any blank pages between answers • Indicate the question number correctly for the answer in the margin space***
- ***Answer all parts of a single question together • Leave sufficient space between answers***
- ***Draw diagrams wherever necessary***

Essays **(2x10=20)**

1. Classify Adverse Drug Reactions. Describe the procedure involving in detection and reporting of ADRs.
2. Explain drug safety evaluation during pregnancy and lactation. Write the differences in Indian and global pharmacovigilance requirements.

Short Notes **(7x5=35)**

3. Explain basic drug information resources.
4. Discuss the establishment of pharmacovigilance program in a hospital.
5. Write briefly the significance of adverse events following immunization.
6. Discuss the International Classification of Diseases (ICD).
7. Describe briefly the standards for periodic safety update reports.
8. Explain the application of Defined Daily Doses (DDD) in drug utilization research.
9. WHO drug dictionary.

Answer Briefly **(10x2=20)**

10. Schedule Y.
11. What are the chemical classification of drugs.
12. Eudravigilance medicinal product dictionary.
13. Preclinical phase in drug development.
14. Explain vaccine pharmacovigilance.
15. How the safety of drugs can be evaluated in paediatrics.
16. Explain active surveillance.
17. Write about communication with media in pharmacovigilance.
18. Explain spontaneous reports in passive surveillance.
19. Cross sectional study.

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