QP Code: 825006 **Reg. No……**

Eighth Semester B. Pharm Degree Regular/Supplementary Examinations July 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. Write in details about expedited reporting.
2. Explain vaccine failure. Define spontaneous reporting method and describe the characteristics and advantages and disadvantages of this method.

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

3. Explain the different methods of casuality assessment.
4. Describe five categories of Adverse Events Following Immunizations (AEFIs)
5. Explain the post marketing surveillance phase of drug development
6. Describe the importance of drug safety monitoring.
7. Explain communication with regulatory agencies and business partners.
8. Explain WHO international drug monitoring programme.
9. Discuss the role of D & C Act in pharmacovigilance of India.

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

10. Define daily defined doses.
11. What are the therapeutic classification of drugs.
12. Write the pharmacovigilance of vaccines.
13. Explain Med DRA.
14. Define Contract Research Organizations.
15. Define CDSCO.
16. What is stimulated reporting in pharmacovigilance.
17. What is CIOMS working groups.
18. Case control study.
19. Explain sentinel sites in active surveillance.

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