QP Code: 825006 **Reg. No…….**

Eighth Semester B. Pharm Degree Regular Examinations May 2022
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. Discuss the roles of Pharmacist in the management and monitoring of ADRs.
2. Describe the genesis and development of Pharmacovigilance in India.

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

3. Explain the Hartwig's severity assessment of adverse drug reactions.
4. Describe good clinical practice in pharmacovigilance studies. .
5. Discuss toxicity studies in schedule Y
6. Explain the objectives of ICH and discuss in detail about its organization.
7. Explain communication in drug safety crisis management
8. Write the ICH standards for individual case safety reports (ICSRs)
9. Explain the functions of Contract Research Organisations in pharmacovigilance

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

10. Cohort study.
11. Define ADRs
12. What are the anatomical classification of drugs
13. What is drug event monitoring in active surveillance.
14. What is the clinical phase in drug development.
15. What are the CIOMS requirements for ADR reporting.
16. What is the role of genes in ADRs.
17. What are the drug safety evaluation in Geriatrics.
18. Passive surveillance.
19. What are CIOMS working groups.

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