QP Code: 825006 **Reg. No…….**

Eighth Semester B. Pharm Degree Regular/Supplementary Examinations July 2023
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 in detail about WHO International Drug Monitoring Programme
2. Define and classify ADRs. Write in detail about management of ADR

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

3. Explain about Detection and Reporting of ADR
4. CIOMS Form
5. Describe about the role of D & C Act in pharmacovigilance
6. Drug safety evaluation in pregnancy and Lactation
7. Explain about Good Clinical Practice in Pharmacovigilance
8. Clinical phase of safety data generation
9. Active surveillance

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

10. Give the Importance of Vaccine Pharmacovigilance
11. Name some specialized resources for ADRs
12. MedDRA
13. Daily defined doses
14. Mention about Eudravigilance Dictionary
15. What are Case-series
16. Pharmacovigilance Planning
17. Contract research organization in Pharmacovigilance
18. Give ICH guidelines about Periodic Safety Update Reports
19. Stimulated reporting

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