QP Code: 825006 **Reg. No……**

Eighth Semester B. Pharm Degree Regular/Supplementary Examinations March 2025
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. Explain in detail about establishment of Pharmacovigilance program in Hospital and Industry. Discuss about the significance of drug safety monitoring in India
2. Discuss in detail about Clinical trial and its distinctive phases and role of CDSCO in Pharmacovigilance.

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

3. Enumerate various objectives of Pharmacovigilance program
4. Anatomical Therapeutic and Chemical classification of drugs
5. Establishment of Pharmacovigilance programme in CRO (Contract Research Organisation)
6. Write in detail about Communication in drug safety management
7. Elaborate Pharmacovigilance planning
8. Discuss and Distinguish between Indian and global pharmacovigilance requirements.
9. Enumerate applications of Defined Daily Dose in drug utilisation research

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

10. What do you mean by safety signal in pharmacovigilance
11. Define the term Pharmacovigilance
12. Write about WHO herbal dictionary
13. What is eudravigilance
14. Write about tertiary sources of information
15. What is post marketing surveillance
16. Cross sectional studies
17. International Classification of Disease (ICD)
18. Write about ICH members, steering committee and working groups
19. Write the scope of CIOMS

****