

*Supply*

# Rajiv Gandhi University of Health Sciences, Karnataka

VIII Semester B. Pharm Degree Examination – 12-May-2025

**Time: Three Hours**

**Max. Marks: 75**

## PHARMACOVIGILANCE

**Q.P. CODE: 5037**

Your answers should be specific to the questions asked

Draw neat labeled diagrams wherever necessary

All the Questions are compulsory

### LONG ESSAYS

**2 x 10 = 20 Marks**

1. Discuss in detail establishment and operation of drug safety department in a pharmaceutical industry

**OR**

Explain the drug information sources and give the specialized resources for Pharmacovigilance

2. What is Vaccine safety surveillance? Explain in detail different types of pharmacovigilance methods used for passive and active surveillance

### SHORT ESSAYS

**7 x 5 = 35 Marks**

3. Mention the important aspects of ICH guidelines for expedited reporting

**OR**

Role of Pharmacist in management of ADRs

4. Write a note on risk benefit assessment of vaccine

**OR**

What is a periodic safety update report

5. Discuss in detail drug safety evaluation in pregnant and lactating women
6. Discuss the importance of effective communication in Pharmacovigilance
7. Write the ATC classification of drugs
8. Explain in detail about case control study in Pharmacovigilance
9. Describe Organization and functions of ICH

### SHORT ANSWERS

**10 x 2 = 20 Marks**

10. What is Drug event monitoring?
11. List out applications of casualty assessment
12. Define Eudravigilance
13. Benefits of post marketing surveillance
14. Importance of using standard dictionary
15. Define CIOMS
16. Write a note on volunteers involved in clinical phases
17. What is phase III of clinical trials?
18. Classify ADR
19. List any four drugs withdrawn from the market due to safety issues

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