

**IV/IV B. PHARMACY DEGREE EXAMINATIONS, JUNE / JULY -2022**  
**Eighth Semester**  
**PHARMACOVIGILANCE**

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Time : Three Hours

Maximum : 75 Marks

**SECTION - A**

**Answer any FIVE Questions.**

**5x10 = 50 M**

1. Explain drug safety evaluation in
  - a) Pregnancy
  - b) Paediatrics.
2. List out various schedules of D&C Act 1940. Add a note on importance of Schedule Y.
3. List out & explain observational studies in pharmacovigilance methods.
4. Discuss the importance, scope & outcomes of Pharmacovigilance.
5. Write a note on
  - a) Passive surveillance.
  - b) Active surveillance.
6. Describe ADR's related to genetics with examples focusing on P'kinetic parameters.
7. Describe the organisation, objectives and guidelines of ICH.

**SECTION - B**

**Answer any FIVE Questions.**

**5x5 = 25 M**

8. Describe the methods for assessment of Casualty.
9. List out any Drug Information Services in India. Add a note on role of Med DRA.
10. Discuss the importance of establishment of communication with Health care facilities & media.
11. Write the anatomical, therapeutic & chemical classification of Drugs.
12. Discuss in detail about predictability & preventability assessment.
13. Describe the Adverse effects that occur post immunization failure.
14. Explain the role of drug safety evaluation in Geriatrics.

