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DEC-23-0098

**BP-805 ET (Pharmacovigilance)**

**B.Pharm-8th (PCI)**

**Time : 3 Hours** **Max. Marks : 75**

**Note:** The questions paper contains three section I, II, III, Section I is compulsory. Attempt any two questions from section II and attempt any seven questions from section III.

## SECTION-A (10×2=20)

### Short Answer (Compulsory)

1. All the Questions

   (a) What is CROs? Give its two main functions.

   (b) What do you understand by Pediatrics?

   (c) Define Pharmacogenomics.

   (d) What do you mean by ATC?

   (e) Define Surveillance.

   (f) What is schedule Y?

   (g) Define Idiosyncratic Reactions

   (h) What do you mean by thalidomide tragedy?

   (i) Define patient information in Individual case safety report.

   (j) Give any two main objectives of ICH.



## SECTION-B (2×10=20)

### Long Answer (Any Two)

2. Define ADR. Write in detail about different types of ADR and its reporting.

3. Write a detailed note on MedDRA and discuss its functions and constitution.

4. What is CIOMS? Discuss its working groups and forms.

## SECTION-C (7×5=35)

### Short Note Answer (Any Seven)

5. Discuss level of classification used for ATC.

6. Elaborate Vaccine Safety Surveillance.

7. Discuss the scope of pharmacovigilance guidelines in paediatrics.

8. Write a note on safety data generation in clinical phase and preclinical phase.

9. Write a detailed note on Eudravigilance.

10. Discuss the role of pharmacovigilance in a hospital.

11. Define the term communication management. Write in detail about their various types.

12. Write short notes on Post approval expedited reporting.

13. What do you mean by Pharmacovigilance planning? Write in detail about its scope.