

B.Pharm Eighth Semester (C.B.S.) Examination**PHARMACOVIGILANCE (DRUG SAFETY)****Paper—5**

Time : Three Hours]

[Maximum Marks : 80

N.B. :— (1) Question No **1** is compulsory.(2) Solve any **FOUR** questions from remaining.

(3) Draw neat labelled diagram wherever necessary.

(4) Assume suitable data wherever necessary.

(5) Discuss the reaction, mechanism wherever necessary.

(6) Use of electronic calculator is permitted.

1. Solve any **FIVE** :

5×4=20

(A) Explain the role of WHO and CIOMS in Pharmacovigilance.

(B) What is Vigibase ? How it is beneficial in Pharmacovigilance ?

(C) Explain Cohort study.

(D) Explain various causality assessment methods.

(E) Explain various limitations pertaining to drug safety in clinical trials.

(F) Elaborate system organ class of MedDRA.

(G) What are various legislations enacted for drug safety ?

2. (A) What is MedDRA ? Explain various advantages of MedDRA.

6

(B) Explain different structural levels of MedDRA with suitable example.

9

3. Define and classify Adverse Drug Reaction. Explain in detail Type A and Type B adverse drug reactions.

15

4. What is Pharmacovigilance ? Explain various methods of Pharmacovigilance with their advantages and disadvantages.

15

5. Explain Pharmacovigilance in paediatric and pregnant population.

15

6. (A) What is signal in Pharmacovigilance ? How it is detected ? Explain various approaches for signal detection.

7

(B) What is benefit and risk ? How are they assessed ?

8

7. Write short notes on (any **THREE**) :

(A) ICH Guidelines for Pharmacovigilance

(B) Data Mining

(C) Risk Management Plan

(D) Safety Concern of Immunogenicity

(E) Special Cases that fall under Pharmacovigilance.

3×5=15