

B.Sc-M.Sc. dual degree (Toxicology) Examination 2023
Department of Medical Elementology & Toxicology

SEMESTER-V
PAPER TITLE: Pharmacovigilance and Risk Management
PAPER CODE: BTX CC 18

Maximum Marks: 75

Duration of time: 3 Hrs

Note: please write the roll number at the top the answer sheets. Attempt all questions as instructed.

Q1. Very Short Type Questions

(2.5 X10)

Write shortly about the following

- A. PSUR
- B. PBRR
- C. SAE
- D. ADR
- E. Naranjo's Scale
- F. ICH
- G. ADE
- H. Pharmacovigilance
- I. Phase IV
- J. PV Database

2. Short Answer: Attempt any Five out of seven questions

5 X 5

- A. History of Pharmacovigilance
- B. Thalidomide Disaster
- C. Safety monitoring in CTs
- D. Role of Clinical Pharmacist in Pharmacovigilance
- E. WHO's role in PVG
- F. ICH E2C guidelines
- G. Scope of Pharmacovigilance

3. Long-type Questions. (Attempt any two out of four questions)

2 X 12.5

- A. Classify ADRs and write down about mechanism, predisposing factors, causality assessment for ADRs.
- B. Write down about the pharmacovigilance indicators and its rationale, classification and objectives?
- C. Discuss Good Pharmacovigilance Practices in detail?
- D. Write down about atleast 5 softwares used in PVG. Discuss Indian PVG programme?