

School of Medical and Allied Sciences

**Bachelor of Pharmacy
Semester End Examination - Aug 2024**

**Duration : 180 Minutes
Max Marks : 75**

Sem VIII - BPET8005 - PharmacovigilanceGeneral Instructions

Answer to the specific question asked

Draw neat, labelled diagrams wherever necessary

Approved data hand books are allowed subject to verification by the Invigilator

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|-----------|--|--------|
| 1) | List the Basic terminologies used in pharmacovigilance. | K1(2) |
| 2) | Classify cross sectional study | K2(2) |
| 3) | What is the chemical classification of drugs. | K1(2) |
| 4) | Illustrate post approval phase (PMS). | K2(2) |
| 5) | What the specialised resources for ADRs | K1(2) |
| 6) | Explain the Healthcare facilitie. | K2(2) |
| 7) | Define Methods in Causality assessment | K1(2) |
| 8) | Explain the Comparative observational studies. | K2(2) |
| 9) | List the drug safety department in industry | K1(2) |
| 10) | Explain the geriatrics | K2(2) |
| 11) | Apply your knowledge in Good clinical practice in pharmacovigilance studies | K3(5) |
| OR | | |
| | Apply your knowledge in Post approval expedited reporting Pharmacovigilance planning | K3(5) |
| 12) | Simplify Effective communication in Pharmacovigilance. | K4(5) |
| 13) | Apply your knowledge the vaccination failure in Pharmacovigilance | K3(5) |
| 14) | Simplify the ICH Guidelines for Pharmacovigilance. | K4(5) |
| 15) | Apply your knowledge in vaccine safety surveillance | K3(5) |
| 16) | Distinguish the method of Passive and Active surveillance Pharmacovigilance | K4(5) |
| OR | | |
| | Distinguish the methods in Causality assessment | K4(5) |
| 17) | Analyze the ICH Guidelines for Pharmacovigilance. | K4(5) |
| 18) | Elaborate ICH Guidelines for Pharmacovigilance. | K6(10) |
| 19) | Explain the preclinical phase and clinicalphase | K5(10) |
| OR | | |
| | Explain the Pharmacovigilance and its role. | K5(10) |