

Manmohan Technical University Office of the Controller of Examinations Exam Year: 2082, Poush (Model Question)		Exam Roll: Exam Roll in words:	
School: School of Medicine and Allied Health Sciences		Level: Bachelor	Invigilator's Sign:
Program: B.Pharmacy		Year/Part: III/I	Superintendent's Sign:
Subject: Drug & Poisons Information & Pharmacovigilance (BP507 ELE)			Code No.

GROUP A (Multiple-Choice Questions)	[10x1=10]	Time: 20 Minutes
<i>i. This group contains 10 multiple-choice questions (MCQs).</i> <i>ii. Answers must be marked on the MCQ Answer Sheet.</i> <i>iii. You may use the main answer sheet for rough work.</i> <i>iv. Marks will not be awarded for answers with cutting, erasing, overwriting, or multiple shaded options.</i> <i>v. The MCQ question paper must be returned along with the MCQ answer sheet.</i>		Code No.:

- Drug Event Monitoring is an example of:
 - Passive surveillance
 - Active surveillance
 - Experimental study
 - Case-control study
- Which of the following is a tertiary drug information resource?
 - PubMed
 - Randomized controlled trial
 - Martindale
 - Clinical trial registry
- The best first step when receiving a phone call about a suspected poisoning is to:
 - Search PubMed for case reports
 - Ask whether the caller has called emergency services and assess ABCs
 - Give activated charcoal immediately
 - Ask for the patient's full medical record
- Naranjo's scale is used for:
 - Severity assessment
 - Causality assessment
 - Predictability assessment
 - Risk-benefit analysis
- Which population is most susceptible to ADR due to immature hepatic metabolism?
 - Elderly
 - Pregnant women
 - Neonates
 - Adults

- Which year did WHO start the International Drug Monitoring Programme?
 - 1958
 - 1968
 - 1978
 - 1988
- The ICH E2E guideline deals with:
 - Clinical trial design
 - Good Manufacturing Practices
 - Pharmacovigilance Planning
 - Drug Pricing Policies
- The WHO global database for ADR reports is known as:
 - MedDRA
 - VigiBase
 - SIDER
 - FAERS
- Which of the following is NOT a factor favoring signal detection?
 - Consistency of cases
 - Temporal relationship
 - Absence of rechallenge information
 - Biological plausibility
- Which of the following is a serious adverse event?
 - Mild headache
 - Temporary rash
 - Hospitalization due to reaction
 - Nausea after first dose

Multiple Choice Questions' Answer Sheet

Marks Secured: _____

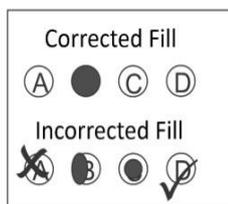
In Words: _____

Examiner's Sign: _____ Date: _____

Scrutinizer's Marks: _____

In Words: _____

Scrutinizer's Sign: _____ Date: _____



1. (A) (B) (C) (D)	6. (A) (B) (C) (D)
2. (A) (B) (C) (D)	7. (A) (B) (C) (D)
3. (A) (B) (C) (D)	8. (A) (B) (C) (D)
4. (A) (B) (C) (D)	9. (A) (B) (C) (D)
5. (A) (B) (C) (D)	10. (A) (B) (C) (D)

Manmohan Technical University
Office of the Controller of Examinations
Exam Year: 2082, Mansir (Model Question)

School: School of Medicine and Allied Health Sciences	Level: Bachelor	Time: 3 Hours
Program: B. Pharmacy	Year/Part: III/I	Full Marks: 50
Subject: Drug & Poisons Information & Pharmacovigilance (BP507 ELE)		Pass Marks: 25

- ✓ Candidates are required to give their answers in their own words as far as practicable.
- ✓ The figures in the margin indicate **Full Marks**.
- ✓ Assume suitable data if necessary.

GROUP A (Multiple-Choice Questions are provided on separate sheet) **[10×1=10]**

GROUP B (Problem Based Question) **[2×5=10]**

1. A patient on warfarin is prescribed trimethoprim-sulfamethoxazole. The clinician asks about interaction. Summarize the concern and monitoring steps. 5
2. A physician receives a questionnaire under Prescription Event Monitoring asking about all events in patients taking a new antibiotic. Why is it important to record all events and not only suspected ADRs? 5

GROUP C (Long Answer Questions - Attempt Any Four) **[4×5=20]**

1. Describe how to establish a poison information centre in a medium-sized hospital.
2. Define Adverse Drug Reaction (ADR) and discuss its classification with suitable examples.
3. Explain the process of ADR detection, reporting, and regulatory action in pharmacovigilance.
4. Explain the concept, methodology, and significance of Drug Event Monitoring in pharmacovigilance.
5. Explain the importance of safety monitoring in pharmacovigilance and its role in public health.
6. Discuss the risk groups prone to adverse drug reactions and explain why these groups require special monitoring.

GROUP D (Short Answer Questions - Attempt Any Five) **[5×2=10]**

1. Define drug information (DI) and poison information (PI) and state one key difference.
2. List the challenges in evaluating drug safety in pregnant women.
3. Define pharmacovigilance. Write any three aims of pharmacovigilance.
4. Write two differences between spontaneous reporting and DEM.
5. Define safety monitoring in pharmacovigilance. List four important sources of safety reports.
6. Describe dose-response relationship in signal assessment.