Name:

Enrolment No:

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES

End Semester Examination, May 2023

Course: Pharmacovigilance I **Semester:IV**

Program: B. Sc. & Int. B. Sc- M. Sc. Clinical Research **Duration: 3 Hours**

Course Code:HSCR2009 **Max. Marks: 100**

Instructions: All the sections are compulsory

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q 1	To date, there are ___CIOMS working groups?	1.5	CO2
Q 2	What is full form of MedDRA?	1.5	CO1
Q 3	Define causality and mention any causality assessing method?	1.5	CO1
Q 4	Define Pharmacogenomics.	1.5	CO1
Q 5	What should a narrative of ADR consist of?	1.5	CO2
Q 6	The frequency of experiencing adverse drug event X for a given drug can be determined through spontaneous reporting systems. True or False?	1.5	CO2
Q 7	Mention the role of clinical pharmacist in Pharmacovigilance.	1.5	CO2
Q 8	What is VigiBase?	1.5	CO1
Q 9	MedDRA is developed by a) ICH b) WHO c) CDSCO d) PCI	1.5	CO2
Q 10	What do you understand by Defined Daily Dose (DDD)	1.5	CO2
Q 11	List down the least criteria required for a valid case?	1.5	CO2
Q 12	Type B adverse reactions are: A) Dose independent. B) predictable. C) Dose dependent. D) Idiosyncratic.	1.5	CO1
Q 13	Define passive surveillance?	1.5	CO1
Q 14	Who is responsible for WHO international drug monitoring Programme?	1.5	CO1
Q 15	Enlist the objectives of ICH?	1.5	CO1
Q 16	Safety data is only collected during the later phases of the clinical development program for a medical product.	1.5	CO2

	True or False?		
Q 17	Pharmacovigilance programme of India was started by Govt of India on ……..	**1.5**	**CO1**
Q 18	Enlist any two objectives of CIOMS ?	**1.5**	**CO2**
Q 19	What do you understand by Dechallenge and rechallenge?	**1.5**	**CO2**
Q 20	A safety signal could be: A. new, previously unknown, adverse event B. A new drug interaction C. An observed change in quantity, severity, or in the affected population of a known adverse event D. All of the above	**1.5**	**CO2**
Section B (4Qx5M=20 Marks)			
Q 1	Discuss the drug safety evaluation in Geriatrics & Pregnanent Population.	**5**	**CO4**
Q 2	Mention the characteristics of Naranjo Adverse drug reaction probability scale?	**5**	**CO3**
Q 3	Write a short note on Pharmacogenomics of adverse drug reactions.	**5**	**CO3**
Q 4	Define adverse drug reactions. Classify ADRs with suitable examples.	**5**	**CO1, CO4**
Section C (2Qx15M=30 Marks)			
Q 1	A 52 year-old patient commenced on allopurinol 300mg for the prevention of another acute attack of gout that recently occurred. The patient is known to have moderate to severe renal impairment, but no liver impairment present. Other concomitant medicines: • iron sorbitol • insulin (short and long acting) • calcium carbonate In the 6th week after starting the medicine, the patient developed severe aplastic anaemia and died. **Q (i)** - The aplastic anaemia and subsequent death are adverse events but are they an ADR? **Q (ii)** - What is the likelihood that the aplastic anaemia is associated with allopurinol?	**15**	**CO2**

	a. Probable b. Possible c. Unlikely **Q (iii)** - Did the patient have any risk factors for prescribing the allopurinol? **Q (iv)** - Was the dose prescribed by the doctor appropriate for the patients' renal function? **Q (v)** - Is aplastic anaemia a possible known side-effect with allopurinol? **Q (vi)** - Which of the following factors possibly contributed to the harm in this patient? a. Poor knowledge of the prescriber on the dosing in renal impairment b. Elderly patient c. Low therapeutic index medicine d. Lack of knowledge of possible side-effects of the medicine e. Genetic factors f. Hepatic or renal impairment g. Compliance problems		
Q 2	Write a note on the following: a) Council for International Organisations of Medical Sciences. b) Pharmacovigilance databases. c) Pharmacovigilance Indicators.	**15**	**CO3**
Section D (2Qx10M=20 Marks)			
Q 1	Write a note on pharmacovigilance programme of India (PvPI)? and explain the process of ADR reporting in India.	**10**	**CO3**
Q 2	Explain briefly Schedule Y of D&C Act.	**10**	**CO3**