Name:

Enrolment No:

UPES

End Semester Examination, May 2024

Course: Pharmacovigilance I **Semester: IV**

Program: B.Sc. (Clinical Research) & Integrated (B.Sc.) - (M.Sc.) Clinical Research **Duration: 03 Hours**

Course Code: HSCR2009 **Max. Marks: 75**

Instructions: All the sections are compulsory.

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q 1	Define ATC classification system of drug and disease.	1.5	CO1
Q 2	Give an example of a Type B ADR.	1.5	CO2
Q 3	Enlist any two key functions of CROs in management of ADRs.	1.5	CO1
Q 4	How does pharmacovigilance practice determine the severity of an ADR?	1.5	CO2
Q 5	Name the regulatory body for medical devices in India.	1.5	CO1
Q 6	Highlight the significance of the periodic safety update report in pharmacovigilance.	1.5	CO2
Q 7	Enlist the key objectives of pharmacovigilance.	1.5	CO1
Q 8	Drug & Cosmetics Rule, 1945: Rules 122D is applicable for the: a) Permission to Import of Drugs b) Approval to Manufacture of Drug c) Permission to import/manufacture Fixed Dose Concentration d) Permission to conduct Clinical Trials	1.5	CO2
Q 9	Which one of these is a genetically determined adverse drug reactions? a) Addication. b) Teratogenecity. c) Carcinogenicity. d) Idiosyncracy.	1.5	CO2
Q 10	Name CIOMS was adopted in: a) 1949 b) 1952 c) 1958	1.5	CO2

	d) 1979		
Q 11	Write any two key objectives of WHO collaborating center in pharmacovigilance.	**1.5**	**CO1**
Q 12	Define predictability and preventability in pharmacovigilance.	**1.5**	**CO1**
Q 13	Define causality.	**1.5**	**CO1**
Q 14	Naranjio scale method of causality assessment is - a) Algorithmic method b) Probabilistic method c) Global introspection d) Algebraic Method	**1.5**	**CO1**
Q 15	What is MedDRA in pharmacovigilance?	**1.5**	**CO1**
Q 16	Define Pharmacogenomics.	**1.5**	**CO1**
Q 17	What are the primary objectives of pharmacovigilance law?	**1.5**	**CO1**
Q 18	Define Dechallenge.	**1.5**	**CO1**
Q 19	Define special population in context of Pharmacovigilance.	**1.5**	**CO1**
Q 20	What does the "quality of reports" indicator measure in a pharmacovigilance system?	**1.5**	**CO2**
	Section B **(4Qx5M=20 Marks)**		
Q 1	Write a short note on CIOMS and its working groups.	**5**	**CO2**
Q 2	Enlist the WHO pharmacovigilance collaborating centers. Discuss role and responsibilities of any two centers.	**(1+4)**	**CO3**
Q 3	Write the differences between Indian and global pharmacovigilance requirements.	**5**	**CO3**
Q 4	Discuss the drug safety evaluation in Pediatrics and Geriatrics population.	**5**	**CO4**
	Section C **(2Qx15M=30 Marks)**		
Q 1	The patient is a 72-year-old male with Type 2 diabetes, hyperlipidemia, and hypertension. He has no history of liver disease.	**(3+3+3 +3+3)**	**CO4**

	Background: • Started Drug X on Feb 11, 2016 • Other medications: simvastatin and lisinopril • Labs drawn on Feb 11 revealed liver enzymes, INR, creatinine, and bilirubin all within normal limits • No alcohol use • 8 weeks after starting Drug X, patient presented to ER with 5- day history of jaundice, dark urine, and nausea/vomiting • He was admitted to ICU and subsequently diagnosed with acute liver failure • Drug X stopped upon admission • Viral hepatitis was ruled out • 7 days after stopping the medication, all lab values returned to normal **Q (i)** List two reasons why this patient may be at risk for an adverse event. **Q (ii)** Is a temporal relationship of acute liver failure with drug X reported in this case? Yes or No (Justify) **Q (iii)** Based on the information on recovery of acute liver failure reported in this case, the patient experienced: A. Positive rechallenge B. Negative dechallenge C. Positive dechallenge D. Negative rechallenge (Justify) **Q (iv)** Name two characteristics in this case that support a causal association of acute liver failure with Drug X. (Justify) **Q (v)** Based on this case, should regulatory action be taken to add acute liver failure to the label? If not, what additional information may be helpful? (Justify)		
Q 2	Write a note on the following: a) Role of clinical pharmacist in Pharmacovigilance. b) Pharmacovigilance databases. c) Aspect of pharmacovigilance laws in pharmacovigilance regulation.	**(5+5+5)**	**CO3**
Section D **(2Qx10M=20 Marks)**			
Q 1	Discuss the responsibilities of sponsors, investigators, and ethical committees in compliance with Schedule Y.	**10**	**CO3**
Q 2	Discuss the structure of Pharmacovigilance Program of India (PVPI) and highlight its scopes and objectives. Explain the process of ADR reporting in India.	**10**	**CO4**