Name:

Enrolment No:

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES

End Semester Examination, December 2022

Course: Pharmacovigilance II **Semester: V**

Program: B. Sc. (Clinical Research) **Duration: 3 Hours**

Course Code: HSCR3002 **Max. Marks: 100**

Instructions:

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q 1	What is Periodic Safety Update Report?	1.5	CO1
Q 2	Name the regulatory bodies of US and Canada?	1.5	CO2
Q 3	What are the objectives of an SOP document?	1.5	CO1
Q 4	What do you understand by good pharmacovigilance process?	1.5	CO2
Q 5	What is a Contract Research Organization (CRO)?	1.5	CO2
Q 6	What are the minimum criteria required for a valid case?	1.5	CO2
Q 7	When do you consider an event to be serious?	1.5	CO1
Q 8	What is CIOMS?	1.5	CO2
Q 9	What is the frequency for MedDRA updates ?	1.5	CO2
Q 10	Define cohort study?	1.5	CO2
Q 11	A safety signal could be: A. 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	CO1
Q 12	What is targeted clinical investigations?	1.5	CO2
Q 13	Define active surveillance?	1.5	CO2
Q 14	Health care providers are required to report all adverse drug events. True or False?	1.5	CO1
Q 15	What is the role of Pharmacovigilance on Vaccines Control ?	1.5	CO1
Q 16	When GVP guidelines were implemented and which of the modules are relevant for ICSR ?	1.5	CO2
Q 17	Give two advantages of a Cross-Sectional Study?	1.5	CO2
Q 18	What do you mean by causality?	1.5	CO2
Q 19	What are the objectives of AEFI detection?	1.5	CO2

Q 20	What is a AE and how is it different from ADR?	**1.5**	**CO2**
	Section B **(4Qx5M=20 Marks)**		
Q 1	Which information should be included in the 'adverse reaction reporting form'? Elaborate.	**5**	**CO1**
Q 2	Enlist the various pharmacovigilance database? Discuss roles and responsibilities of any two in detail?	**5**	**CO3**
Q 3	Explain Pharmacovigilance Program of India (PvPI)?	**5**	**CO3**
Q 4	Describe the pharmacovigilance communications and pharmacoepidemiology studies?	**5**	**CO4**
	Section C **(2Qx15M=30 Marks)**		
Q 1	The patient is a 59-year-old male with Type 2 diabetes, hyperlipidemia, and hypertension. He has no history of liver disease. **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 **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	**15**	**CO1**

	C. Positive dechallenge D. Negative rechallenge **Q (iv)** Name two characteristics in this case that support a causal association of acute liver failure with Drug X. **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?		
Q 2	What is pharmacovigilance audits? Discuss the types and quality cycle of pharmacovigilance system audits ?	**15**	**CO3**
Section D (2Qx10M=20 Marks)			
Q 1	Write down two examples or cases of expedited reporting with explanations?	**10**	**CO4**
Q 2	Write a note on the following: a) Case narrative writing b) Case processing in pharmacovigilance	**10**	**CO1**