Name:

Enrolment No:

UPES

End Semester Examination, December 2023

Course: Pharmacovigilance II **Semester: V**

Program: B.Sc.(Clinical Research)/Int.(B.Sc.+M.Sc.(Clinical Research)) **Duration: 3 Hours**

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

Instructions: All questions are compulsory.

S. No.	Section A Short answer questions/ MCQ (20Qx1.5M= 30 Marks)	Marks	COs
Q 1	What is periodic safety update report?	**1.5**	**CO1**
Q 2	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**	**CO2**
Q 3	What are the objectives of an SOP document?	**1.5**	**CO2**
Q 4	What do you understand by good pharmacovigilance process?	**1.5**	**CO2**
Q 5	What is the frequency for MedDRA updates?	**1.5**	**CO1**
Q 6	What is AE and how is it different from ADR?	**1.5**	**CO2**
Q 7	When do you consider an event to be serious?	**1.5**	**CO2**
Q 8	Name commonly used Software's in Pharmacovigilance?	**1.5**	**CO1**
Q 9	What is the purpose of EudraVigilance?	**1.5**	**CO2**
Q 10	Define cohort study.	**1.5**	**CO2**
Q 11	What is the objective of CIOMS in PV?	**1.5**	**CO1**
Q 12	What is targeted clinical investigations?	**1.5**	**CO1**
Q 13	Expand the term CDSCO.	**1.5**	**CO1**
Q 14	What is the primary purpose of a case narrative in pharmacovigilance?	**1.5**	**CO2**
Q 15	What is the role of Pharmacovigilance on vaccines control?	**1.5**	**CO2**
Q 16	Define pharmacogenomics.	**1.5**	**CO1**
Q 17	Enlist 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 primary objectives of Phase-1 clinical trial?	**1.5**	**CO2**
Q 20	Define stimulated reporting.	**1.5**	**CO1**

Section B **(4Qx5M=20 Marks)**			
Q 1	Define and classify AEFI.	**1+4**	**CO2**
Q 2	What is expedited reporting? Highlight the key data elements for inclusion in expedited reporting.	**1+4**	**CO3**
Q 3	Discuss the key activities of ISoP.	**5**	**CO3**
Q 4	Highlight the various factors to be considered for setting up pharmacovigilance center in hospital.	**5**	**CO4**
Section C **(2Qx15M=30 Marks)**			
Q 1	What is Vaccine safety surveillance? Explain in detail different types of pharmacovigilance methods used for passive and active surveillance.	**2+13**	**CO4**
Q 2	Write a note on the following: **a)** Pharmacovigilance communications. **b)** Contract research organizations. **c)** Case processing in pharmacovigilance.	**5+5+5**	**CO3**
Section D **(2Qx10M=20 Marks)**			
Q 1	Differentiate between audit and inspection. Discuss the types of pharmacovigilance audits.	**3+7**	**CO4**
Q 2	Explain the various aspects of safety monitoring in clinical trials.	**10**	**CO4**