Name: **Enrolment No:**	UPES UNIVERSITY OF TOMORROW

UPES
End Semester Examination, May 2025

Course: Pharmacovigilance
Program: B. Pharm
Course Code: BP805ET

Semester: VIII
Duration: 03 Hours
Max. Marks: 75

Instructions: Attempt all the sections.

SECTION A
(20Qx1M=20 Marks)

S. No.	Attempt all.	Marks	COs
Q. 1.	What is Pharmacogenomics?	**1**	**CO1**
Q. 2.	Classify ADRs.	**1**	**CO1**
Q. 3.	Who are the stakeholders in safety monitoring?	**1**	**CO1**
Q.4.	Define case control study.	**1**	**CO1**
Q. 5.	What is CIOMS?	**1**	**CO2**
Q. 6.	State difference between adverse drug events and adverse drug reaction.	**1**	**CO2**
Q.7.	The Pharmacovigilance Programme of India (PvPI) was established in year_____.	**1**	**CO2**
Q. 8.	_____ classification of drugs as per WHO guidelines.	**1**	**CO2**
Q. 9.	Health care providers are required to report all adverse drug events. True or False?	**1**	**CO3**
Q. 10.	Medication error define as _____.	**1**	**CO3**
Q. 11.	What is pre clinical phase?	**1**	**CO3**
Q. 12.	State schedule Y.	**1**	**CO3**
Q. 13.	Define MedDRA.	**1**	**CO4**
Q.14.	Define targeted clinical investigations	**1**	**CO4**
Q. 15.	Differentiate between AE and ADR.	**1**	**CO4**
Q. 16.	State use of good communication in pharmacovigilance.	**1**	**CO4**
Q.17.	Define cohort study?	**1**	**CO5**
Q. 18.	In international nongovernmental organization established jointly by World Health Organization (WHO) and United Nations Educational, Scientific and Cultural Organization (UNESCO) in 1949 is CIOMS, CIOMS is ……	**1**	**CO5**
Q. 19.	Define Eudravigilance.	**1**	**CO5**
Q. 20.	Name the regulatory bodies of US and Canada.	**1**	**CO5**

SECTION B (20 Marks)
(2Qx10M=20 Marks)
Attempt ANY 2 Question out of 3

Q 1	Write a note on the history and development of pharmacovigilance.	**10**	**CO1**
Q. 2.	Write a note on drug safety evaluation on **any two**	**5+5= 10**	**CO3**

	a) pediatrics b) geriatrics c) pregnancy and lactation		
Q. 3.	From the below case report state your analysis and justify your answer play the clear statement. A patient who was taking 40 mg of omeprazole daily. After a month she developed interstitial nephritis. She was not taking other medicines. The outcome was reported as not recovered. The outcome of the dechallenge was unknown. On rechallenge the main reaction was reported to have recurred. Is that a certain report? There was a recurrence on rechallenge and there were no dates in the report.	**10**	**CO5**
SECTION-C (35 Marks) **(7Qx5M=35 Marks)** **Attempt ANY 7 Question out of 9**			
Q 1	Write a difference between passive and active surveillance.	**5**	**CO1**
Q. 2.	Describe the overall process of pharmacovigilance.	**5**	**CO1**
Q. 3.	Discuss Good clinical practice in pharmacovigilance studies.	**5**	**CO2**
Q.4.	Write a note on PSUR.	**5**	**CO2**
Q. 5.	Write a note on Pharmacovigilance Program of India (PvPI).	**5**	**CO3**
Q. 6.	Discuss in detail on national and international scenario of pharmacovigilance.	**5**	**CO3**
Q.7.	Write a difference between cohort study and cross-sectional study.	**5**	**CO4**
Q. 8.	Discuss different forms of CIOMS.	**5**	**CO5**
Q. 9.	Describe the Pharmacogenomics of adverse drug reactions.	**5**	**CO5**