Name: **Enrolment No:** **SAP ID:**	UPES UNIVERSITY WITH A PURPOSE

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES
End Semester Examination, November 2021

Course: MSc-Chemistry **Semester: III**
Program: Pharmacovigilance **Time: Three hours**

Course Code: HSCR8010 **Max. Marks: 100**

SECTION A

Instructions:
Each question will carry 5 marks

Q 1	What do you mean by pharmacovigilance? What are the objectives of pharmacovigilance study?	**1+4**	**CO1**
Q 2	What do you mean by ADR? Is ADR and ADE same? Explain it. What is the difference between ADR and side effects?	**1+2+2**	**CO3**
Q 3	Write down the current scope of pharmacovigilance during clinical trails of drugs	**5**	**CO1**
Q 4	What is drug-drug interactions? Write down the different types of drug-drug interactions with at least one example.	**2+3**	**CO3**
	SECTION B **Instructions:** **Each question will carry 10 marks**		
Q 6	Write down the names of different causality assessment methods of ADR used in pharmacovigilance. Explain any three of them.	**10**	**CO3**
Q 7	Write down the different classifications of ADR with proper explanations and examples.	**10**	**CO3**
Q 8	a) Write a short note on Pharmacovigilance Risk Assessment Committee (PRAC). b) Shortly discuss the roles of various regulatory agenesis to control the pharmacovigilance study in India.	**5+5**	**CO2**
Q 9	a) Define the term "International Non- Proprietary Name (INN)". b) What is the use of INN? c) Define "School of INN". d) What is the role and function of "SoINN"?	**2+3+2 +3**	**CO1**
	SECTION C **Instructions:** **Each question will carry 20 marks**		

Q 10	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. a) The aplastic anaemia and subsequent death are adverse events but are they an ADR? Yes or No. b) What is the likelihood that the aplastic anemia is associated with allopurinol? Probable 1. Possible 2. Unlikely c) Did the patient have any risk factors for prescribing the allopurinol? d) Was the dose prescribed by the doctor appropriate for the patients' renal function? e) How will you report this serious adverse event? f) What type of Adverse Drug Reaction is this? Discuss the Pharmacovigilance methods used for ADR detection?	**1+2+2 +2+6+ 2+5**	**CO3**
Q 11	a) What do you mean by safety database under FDA guidance? b) Write a short note on safety data collection. c) What do you mean by NPP? Explain different steps involved in this protocol? d) Discuss the ICH- Periodic Safety Update reports for Marketed Drugs.	**2+6+2 +6+4**	**CO1, CO4**