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

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES
End Semester Examination, May 2022

Course: Pharmacovigilance I **Semester: IV**
Program: BSc Clinical Research **Time: 03 hrs.**
Course Code: HSCR2009 **Max. Marks: 100**

Instructions: Attempt all Sections.

SECTION A

S. No.	**MCQs or True and False or Fill in the blanks (1.5 marks each)**	**30**	**CO**
1	The incidence ADR is highest in _____. a) Children b) Elderly c) Women d) Men	**1.5**	**CO1**
2	Which of the following adverse drug reactions would you report to the Medicines and Healthcare Products regulatory Agency (MHRA) via the yellow card system for reporting? a. A patient reports nausea after starting a course on amoxicillin capsules. b. A patient reports experiencing cough when they take their indomethacin capsules. c. A patient complains of nausea since they have started taking ramipril. d. A patient complains of diarrhea since they have started taking azilsartan.	**1.5**	**CO2**
3	Which of the following patients are most at risk of suffering from an adverse drug reaction? a. An 8-month year old infant receiving a prescription for an antibiotic. b. A 22-year-old patient with asthma receiving prescriptions for inhalers to relieve and prevent their asthma. c. A 48-year-old patient who has hypertension and receives a prescription for an ACE inhibitor. d. A 68-year-old patient who has edema receiving a prescription for a diuretic.	**1.5**	**CO3**
4	_____ is contraindicated during pregnancy due to its Teratogenicity. a) Folic acid b) Calcium c) Retinol d) Iron	**1.5**	**CO1**
5	GCP are seen in all of the following except a) Phase I trial b) Phase II trial c) Preclinical trials d) Phase IV trial	**1.5**	**CO2**
6	Idiosyncrasy is_____. a) Type A ADRs b) Type B ADRs	**1.5**	**CO3**

	c) Type C ADRs d) Type D ADRs		
7	Pharmacovigilance is done for monitoring of a) Drug price b) Unethical practices c) Drug safety d) Pharmacy students	**1.5**	**CO1**
8	Patient counselling helps to a) Know chemical structure of drug b) Develop business relations with pharmacist c) Motivate the patient to take medicine for improvement of his/her health status. d) Pass time at old age	**1.5**	**CO2**
9	A 75-year-old man had been receiving gentamicin (an aminoglycoside antibiotic) to treat urinary tract infection. After three months of therapy patient's serum creatinine levels were 10 mg/dL (normal 0.5-1.2) and serum gentamicin concentrations obtained just before the last dose were 9 mg/dL (normal < 2). Which of the following is the most likely adverse drug reaction the patient was suffering from? a) Type II allergic reaction b) Type III allergic reaction c) Pseudo allergic reaction d) Overdose toxicity	**1.5**	**CO3**
10	What are Good Clinical Practices? a. Regulations set in place by Government that how clinical trials are supposed to be managed. b. Clinical practices that adhere to the best standards of care. c. Widely accepted standards of practice during clinical trials d. The FDA's requirements for how trials are conducted and documented	**1.5**	**CO1**
11	Which of the following medication is safe to use in the third trimester of pregnancy? a. Acetaminophen B. Warfarin C. Aspirin D. Oxycodone	**1.5**	**CO2**
12	……is the field name for the World Health Organization Collaborating Centre for International Drug Monitoring. a. Uppsala Monitoring Centre b. MedDRA c. Europe FDA d. Vigibase	**1.5**	**CO3**
13	Individual safety case report (ICSR) should summarize all the following information except: a) Post-mortem/ autopsy findings b) Medical reviewer's evaluation and comment c) Pre-approval expedited reports d) Information in the chronology of patient experience	**1.5**	**CO1**
14	The……. is the United Kingdom's system for collecting information on suspected adverse drug reactions (ADRs) to medicines.	**1.5**	**CO2**

	a. Black box b. Yellow card scheme c. Cohort Reports d. Red Flag		
15	Adverse Event is due to – a) Life threatening b) Due to drug/treatment c) May or may not have causal relationship with treatment d) None of above	**1.5**	**CO3**
16	…… is a clinically validated medical terminology dictionary, designed for use in the registration, documentation, and safety monitoring of medicinal products through all phases of the development life cycle. a. Uppsala Monitoring Centre b. MedDRA c. Europe FDA d. Vigibase	**1.5**	**CO1**
17	……. is generally regarded as the study or clinical testing of genetic variation that gives rise to differing responses to drugs, including adverse drug reactions.	**1.5**	**CO2**
18	To begin clinical research study, it is mandatory to get approval from? a). Sponsor b). Regulator c). Regulators and ethics committee d). ethics committee	**1.5**	**CO3**
19	A serious adverse event (SAE) in human drug trials is defined as any untoward medical occurrence that at any dose. a. Result in death b. Is life threatening c. Requires in-patient hospitalization d. All of the above	**1.5**	**CO1**
20	The Pharmacovigilance Programme of India (PvPI), coordinated by the Indian Pharmacopeia Commission, is situated at a) Calcutta b) Mumbai c). Ghaziabad d) Jaipur	**1.5**	**CO2**
SECTION B the word limit 20 marks 4 questions 5 marks each			
Q	**Short Answer Type Question (5 marks each)**	**20**	**CO**
1	What do you mean by pharmacovigilance? What are the objectives of pharmacovigilance study?	**1+4**	**CO1**
2	What is drug-drug interactions? Write down the different types of drug-drug interactions with at least one example.	**1+4**	**CO2**
3	What is Spontaneous Reporting? Mention in points what to report in spontaneous reporting.	**2+3**	**CO2**

4	What is individual Case safety Report? How to determine the onset of an adverse reaction?	**2+3**	**CO1**
	SECTION C 30 marks		
Q	**Long Answer type Questions (15 marks each)**	30	**CO**
1	a) What do you mean by safety database under FDA guidance? (2 marks) b) Write a short note on safety data collection. (5 marks) c) What do you mean by NPP? Explain different steps involved in this protocol? (4 marks) d) Discuss the ICH- Periodic Safety Update reports for Marketed Drugs. (4 marks)	**15**	**CO3** **CO5**
2	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. 1. The aplastic anemia and subsequent death are adverse events but are they an ADR? Yes or No. (1 mark) 2. What is the likelihood that the aplastic anemia is associated with allopurinol? (2 mark) a. Probable b. Possible c. Unlikely 3. Did the patient have any risk factors for prescribing the allopurinol? Yes or No. (1 mark) 4. Was the dose prescribed by the doctor appropriate for the patients' renal function? Yes or No. (1 mark) 5. How will you report this serious adverse event? (5 marks) 6. What type of Adverse Drug Reaction is this? (1 marks) 7. Discuss the Pharmacovigilance methods used for ADR detection? (4 marks)	**15**	**CO3** **CO5**
	SECTION- D 20 marks		
Q	**Long Answer type Questions (10 marks each)**	**20**	**CO**
1	a) Define the term “International Non- Proprietary Name (INN)”. (2 marks) b) What is the use of INN? (3 marks) c) Define “School of INN”. (2 marks) d) What is the role and function of “SoINN”? (3 marks)	**10**	**CO4**
2	a) Write a short note on Pharmacovigilance Risk Assessment Committee (PRAC). (5 marks) b) Shortly discuss the roles of various regulatory agenesis to control the pharmacovigilance study in India. (5 marks)	**10**	**CO4**