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

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

Course: Pharmacovigilance **Semester: II**
Program: MSc Clinical Research / Micro **Time: 03 hrs.**
Course Code: HSCR 7012 **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 c) Type C ADRs d) Type D ADRs	**1.5**	**CO3**

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	A WHO global individual case safety report database…… is maintained and developed on behalf of the WHO by Uppsala Monitoring Centre.	**1.5**	**CO1**
14	The…….. is the United Kingdom's system for collecting information on suspected adverse drug reactions (ADRs) to medicines. a. Black box b. Yellow card scheme c. Cohort Reports d. Red Flag	**1.5**	**CO2**

15	…… 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**	**CO3**
16	An 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 ……	**1.5**	**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	…….is the European data processing network and management system for reporting and evaluation of suspected adverse reactions to medicines which have been authorized or being studied in clinical trials.	**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	……. is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment.	**1.5**	**CO2**
	SECTION B (for each answer word limit not more than 200 words)		
Q	Short Answer Type Question (5 marks each) Scan and Upload 4 questions 5 marks each	**20**	**CO**
1	Discuss ICH-Periodic Safety Update reports for Marketed Drugs.	**5**	**CO1**
2	What is ICD? Explain with example the coding of diseases under ICD classification.	**2+3**	**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		
Q	**Two case studies 15 marks each subsections**	30	**CO**
1	With burgeoning reports of adverse drug reactions due to pharmacotherapy, pharmacovigilance (PV) is the buzzword in health care circles. While there are experts in this rapidly expanding field, many health care professionals do not fully appreciate the import of PV in the context of modern therapeutics. In view of the national directive to institutionalize a PV center in every medical college of India, there is an urgent need to inform, educate, and enlighten about the constitution and dynamics of a PV center. 1. Why there is a need of Pharmacovigilance Program? (3 marks)	**15**	**CO3, CO5,**

	2. What are the basics required in establishing a pharmacovigilance centre? (4 marks) 3. What measures must be adopted for good ADR reporting culture? (4 marks) 4. What are the role and responsibilities of Pharmacovigilance Centre? (4 marks)		
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 anaemia 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		
Q	Long Answer Type (Scan and Upload)	**20**	**CO**
1	Define the term “International Non- Proprietary Name (INN)”. (2 marks) What is the use of INN? (3 marks) Define “School of INN”. (2 marks) What is the role and function of “SoINN”? (3 marks)	**10**	**CO4**
2	What are the Pharmacogenomics approaches used to identify causative genes? (2 marks) What is HLA? (2 marks) How HLA gene acts as a risk factor for adverse drug reactions? (4 marks) Give examples (2 marks)	**10**	**CO4**