

Name:	 UPES UNIVERSITY WITH A PURPOSE
Enrolment No:	

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

Course: Pharmacovigilance	Semester: II
Program: MSc Clinical Research/ Microbiology	Time: 03 hrs.
Course Code: HSCR 7012	Max. Marks: 100
Instructions: Attempt all Sections.	

SECTION A

S. No.	MCQs/ True and False/ Fill in the blanks/ Two line answer (1.5 marks each)	30	CO
1	Define “Eudravigilance”.	1.5	CO1
2	When do you consider an adverse event to be serious? (Any three factors).	1.5	CO2
3	Mention the hierarchy in Med DRA.	1.5	CO3
4	What is Naranjo Scale? (two line answer)	1.5	CO1
5	Mention any three challenges of pharmacovigilance in pediatrics.	1.5	CO2
6	Define “Adverse Event”.	1.5	CO3
7	What is INN (International Non-propriety name for drugs)?	1.5	CO1
8	Which characteristics of diseases are included in classifying diseases under ICD? (mention any three).	1.5	CO2
9	Give the classification of vaccines.	1.5	CO3
10is an individual case safety report (ICSR) management system developed and hosted by Uppsala Monitoring Centre.	1.5	CO1
11	Write the advantages of primary sources of drug information in pharmacovigilance.	1.5	CO2
12	Which of the following is an example of Type B ADRS? a) Hypoglycaemia caused by Insulin b) Dryness of mouth caused by Atropine c) Anaemia in patient with G6PD deficiency caused by Primaquine d) Hyperglycaemia caused by thiazide diuretics	1.5	CO3
13	The age related physiological change in geriatric patient which may affect drug distribution is a) Increased body mass. b) Increased total body water. c) Increased total body fat. d) Increased serum albumin level.	1.5	CO1
14	Define “Teratogenicity”.	1.5	CO2

15	The comparison of bioavailability between two dosage forms is referred as _____ A. Bioavailability B. Biopharmaceutics C. Biological D. Bioequivalence	1.5	CO3
16	How are prescription medicines different from OTC ones? A. They contain much smaller amounts of active ingredients B. They don't contain dyes or preservatives C. They're unsafe for use without medical supervision D. They can be toxic	1.5	CO1
17	Case control studies in pharmacovigilance is known as A. Drug-oriented systems. B. Dose-oriented systems. C. Disease-oriented systems. D. Complication-oriented systems.	1.5	CO2
18	Type I ADR reactions is _____ a) Caused when T-cells bind to a specific antigen b) Caused by tissue injury c) IgE mediated d) Caused by cytotoxic antibodies	1.5	CO3
19	True or False Vaccines contain antigens resembling those of natural infections and stimulate the immune system to make a primary response and a memory response, Booster doses of vaccines reinforce the memory response.	1.5	CO1
20	The Coding Symbols for a Thesaurus of Adverse Reaction Terms (COSTART) was developed by thefor the coding, filing and retrieving of post-marketing adverse reaction reports. a. US-FDA b. EMA c. PMDA d. WHO	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 in detail about passive surveillance and active surveillance methods in pharmacovigilance.	5	CO1
2	What is International classification of disease system? How many international classifications of disease are there? discuss with examples.	2+3	CO2
3	Explain the applications of MedDRA and standard MedDRA queries.	5	CO2
4	Define Adverse Drug Reactions. Classify ADRs with suitable examples.	5	CO1

SECTION C

Q	Two case studies 15 marks each subsections	30	CO
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1	<ol style="list-style-type: none"> 1. Why there is a need of Pharmacovigilance Program? (3 marks) 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) 	15	CO3 , CO5 ,
2	<p>A 67-year-old woman with an extensive rash is referred urgently to hospital. The rash started on the backs of her hands and spread very quickly to the arms, trunk, neck, and face. The lesions consist of concentric rings with frank blistering in some areas. Lesions have also started to appear on her lips and inside her mouth.</p> <p>Her medications include: ramipril 10mg once daily, simvastatin 40mg at night, aspirin 75mg once daily, metformin 1g twice daily, gliclazide 40mg each morning. She was started on aspirin 5 years ago following a stroke. At about the same time, she was diagnosed with type 2 diabetes and has been taking metformin, ramipril, and simvastatin for over 4 years. She was prescribed gliclazide during her annual diabetes review 2 months ago.</p> <p>The patient denies taking any over-the-counter medicines or herbal remedies. She has not made any significant changes to her diet and there is no history of recent infection.</p> <p>On admission: Blood pressure = 127/75 mmHg Body Mass Index = 26kg/m² HbA1c = 8.0% (64mmol/mol)</p> <ol style="list-style-type: none"> 1. Which drug is most likely to be causing erythema multiforme? (1 marks) 2. How should this adverse drug reaction (ADR) be managed? (4 marks) 3. How will you report this serious adverse event? (5 marks) 4. What type of Adverse Drug Reaction is this? (1 marks) 5. Discuss the Pharmacovigilance methods used for ADR detection? (4 marks) 	15	CO3 , CO5 ,
SECTION- D			
Q	Long Answer Type	20	CO
1	What is ICSR? What are the requirements of ICSR? Discuss its importance in pharmacovigilance. (2+3+5)	10	CO4
2	<p>What are the Pharmacogenomics approaches used to identify causative genes? (2 marks)</p> <p>What is HLA? (2 marks)</p> <p>How HLA gene acts as a risk factor for adverse drug reactions? (4 marks)</p> <p>Give examples (2 marks)</p>	10	CO1 . CO2