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| **Name:**<br>**Enrolment No:** | UPES<br>UNIVERSITY OF TOMORROW |

**End Semester Examination, December 2024**

**Course:** Pharmacovigilance-II — **Semester : V**

**Program:** BSC-CLINICAL-RESEARCH — **Duration : 3 Hours**

**Course Code:** HSCR3002 — **Max. Marks: 100**

**Instructions: Read all questions carefully.**

| S. No. | Section A<br>Short answer questions/ MCQ/T&F<br>(20Qx1.5M= 30 Marks)<br>All questions compulsory | Marks | COs |
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| Q 1 | Define the adverse drug reaction | 1.5 | CO1 |
| Q 2 | Discuss the PSUR | 1.5 | CO2 |
| Q 3 | Classify ADRs according to severity. | 1.5 | CO1 |
| Q 4 | Discuss the cohort study with example | 1.5 | CO3 |
| Q 5 | Suggest the requirement for CIOMS form | 1.5 | CO2 |
| Q 6 | Narrate the minimum criteria required for a valid report | 1.5 | CO2 |
| Q 7 | Mention the basic objectives of pharmacovigilance planning? | 1.5 | CO1 |
| Q 8 | Mention few examples of predictable adverse drug reactions. | 1.5 | CO1 |
| Q 9 | Define Cohort and case control study? With examples | 1.5 | CO1 |
| Q 10 | Mention the applications of MedDRA and standard MedDRA queries. | 1.5 | CO2 |
| Q 11 | Pharmacovigilance is done for monitoring of<br>a. Drug price<br>b. Unethical practices<br>c. Drug safety<br>d. Pharmacy students | 1.5 | CO1 |
| Q 12 | Good Clinical Practices are----<br>a. Regulations set in place by Government that how clinical trials are supposed to be managed.<br>b. Clinical practices that adhere to the best standards of care.<br>c. Widely accepted standards of practice during clinical trials<br>d. The FDA's requirements for how trials are conducted and documented | 1.5 | CO3 |
| Q 13 | ……is the field name for the World Health Organization Collaborating Centre for International Drug Monitoring.<br>a. Uppsala Monitoring Centre<br>b. MedDRA | 1.5 | CO1 |

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| | **c. Europe FDA**<br>**d. Vigibase** | | |
| **Q 14** | **A WHO global individual case safety report database…… is maintained and developed on behalf of the WHO by Uppsala Monitoring Centre.** | **1.5** | **CO2** |
| **Q 15** | **A serious adverse event (SAE) in human drug trials is defined as any untoward medical occurrence that at any dose.**<br>**a. Result in death**<br>**b. Is life threatening**<br>**c. Requires in-patient hospitalization**<br>**d. All of the above** | **1.5** | **CO1** |
| **Q 16** | **The…….. is the United Kingdom's system for collecting information on suspected adverse drug reactions (ADRs) to medicines.**<br>**a. Black box**<br>**b. Yellow card scheme**<br>**c. Cohort Reports**<br>**d. Red Flag** | **1.5** | **CO1** |
| **Q 17** | **GCP are seen in all of the following except**<br>**a. Phase I trial**<br>**b. Phase II trial**<br>**c. Preclinical trials**<br>**d. Phase IV trial** | **1.5** | **CO2** |
| **Q 18** | **……. 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** | **CO3** |
| **Q 19** | **Patient counselling helps to**<br>**a. Know chemical structure of drug**<br>**b. Develop business relations with pharmacist**<br>**c. Motivate the patient to take medicine for improvement of his/her health status.**<br>**d. Pass time at old age** | **1.5** | **CO1** |
| **Q 20** | **Illustrate the objectives of ICH** | **1.5** | **CO2** |
| **Section B**<br>**(4Qx5M=20 Marks)** | | | |
| **Q 1** | **Explain Pharmacovigilance Program of India (PvPI)?** | **5** | **CO2** |
| **Q 2** | **Discuss ICH-Periodic Safety Update reports for Marketed Drugs.** | **5** | **CO2** |
| **Q 3** | **Explain International classification of disease system? How many international classifications of disease are there? discuss with examples.** | **1+2+2** | **CO3** |

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| **Q 4** | **Enlist the various pharmacovigilance database? Discuss roles and responsibilities of any two in detail?**<br>**Or**<br>**Describe the pharmacovigilance communications and pharmacoepidemiology studies?** | **2+3** | **CO2** |
| **Section C**<br>**(2Qx15M=30 Marks)** | | | |
| **Q 1** | **The patient is a 59-year-old male with Type 2 diabetes, hyperlipidemia, and hypertension. He has no history of liver disease. Background: • Started Drug X on Feb 11, 2016 • Other medications: simvastatin and lisinopril • Labs drawn on Feb 11 revealed liver enzymes, INR, creatinine, and bilirubin all within normal limits • No alcohol use • 8 weeks after starting Drug X, patient presented to ER with 5- day history of jaundice, dark urine, and nausea/vomiting • He was admitted to ICU and subsequently diagnosed with acute liver failure • Drug X stopped upon admission • Viral hepatitis was ruled out • 7 days after stopping the medication, all lab values returned to normal**<br>**(i) List two reasons why this patient may be at risk for an adverse event.**<br>**(ii) Is a temporal relationship of acute liver failure with drug X reported in this case? Yes or No**<br>**(iii) Based on the information on recovery of acute liver failure reported in this case, the patient experienced:**<br>**a. Positive rechallenge**<br>**b. Negative dechallenge**<br>**c. Positive dechallenge**<br>**d. Negative rechallenge**<br>**(iv) Name two characteristics in this case that support a causal association of acute liver failure with Drug X.**<br>**(v) Based on this case, should regulatory action be taken to add acute liver failure to the label? If not, what additional information may be helpful?** | **5+1+1+3+ 5** | **CO1** |
| **Q 2** | **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.**<br>**a. Why there is a need for the Pharmacovigilance Program?** | **3+4+4+4** | **CO2** |

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| | **b. Mention the basics required in establishing a pharmacovigilance center?**<br>**c. Discuss the measures that must be adopted for good ADR reporting culture?**<br>**d. Mention the role and responsibilities of Pharmacovigilance Centre?** | | |
| **Section D**<br>**(2Qx10M=20 Marks)** | | | |
| **Q 1** | **Brief about vaccine safety surveillance in the market. Explain the roles of contract research organization and its management.** | **5+5** | **CO2** |
| **Q 2** | **Discuss the different types of pharmacovigilance methods used for passive and active surveillance.** | **5+5** | **CO3** |