Duration: 3 Hours   **Total marks: 80 M**

Note.: 1. All questions are compulsory
   2. Figures to right indicate full marks

Q. 1   Choose appropriate option for following multiple choice based questions.   20

1   Centre for Pharmacovigilance Program of India is located at….

   a.   IPC, Ghaziabad

   b.   CDSCO, New Delhi

   c.   AIIMS, New Delhi

   d.   CDL, Kolkata

2   .... is an Activity associated with Pharmacovigilance.

   a.   Vaccine Safety Surveillance.

   b.   Pre-clinical Drug Development

   c.   Translational Research

   d.   Phase I Clinical Study

3   ICH Guideline entitled Pharmacovigilance Planning……..

   a.   E 2 B

   b.   E 19

   c.   E 2 C

   d.   E 2 E

4   Pharmacovigilance is done for monitoring of………

   a.   Drug Safety

   b.   Drug Price Control

   c.   Animal Experiments

   d.   Toxicokinetic Studies

5   Which One of the following is ICH Efficacy Guideline………..

   a.   Safety Pharmacology Studies

   b.   Good Laboratory Practices

   c.   Bioanalytical Method Validation

   d.   Good Clinical Practices

6 **The MedDRA (Medical Dictionary for Regulatory Activities) is used for:**

    a. Drug registration

    b. ADR coding and classification

    c. Clinical trial design

    d. Drug manufacturing standards

7 **The term "signal" in pharmacovigilance refers to**

    a. Any observable phenomenon after drug administration

    b. A statistically significant association between a drug and an adverse event

    c. An adverse drug reaction reported by a patient

    d. A rare side effect observed in clinical trials

8 **.................... agency is responsible for pharmacovigilance in India.**

    a. USFDA (United States Food and Drug Administration)

    b. MHRA (Medicines and Healthcare products Regulatory Agency)

    c. CDSCO (Central Drugs Standard Control Organization)

    d. EMA (European Medicines Agency)

9 **The WHO Drug Dictionary is used primarily for**

    a. Tracking drug sales

    b. Standardizing drug nomenclature

    c. Assessing drug efficacy

    d. Marketing authorization of new drugs

10 **The causality assessment tool commonly used in pharmacovigilance is**

    a. Naranjo Algorithm

    b. Beers Criteria

    c. Braden Scale

    d. Modified Early Warning Score (MEWS)

11 **.................... is an example of a serious adverse drug reaction**

    a. Mild headache

    b. Nausea and vomiting

    c. Dizziness upon standing up

    d. Anaphylactic shock

12 **----------------- databases is commonly used for spontaneous reporting of adverse drug reactions?**

    a. EudraVigilance

    b. PubMed

    c. Google Scholar

    d. Cochrane Library

13 **....................... regulatory activities falls under the scope of pharmacovigilance**

    a. Approving new drugs

    b. Patenting drug formulations

    c. Recalling unsafe drugs from the market

    d. Setting drug prices

14 **The process of causality assessment in pharmacovigilance aims to**
   a. Identify all potential adverse drug reactions
   b. Establish a definitive link between a drug and an adverse event
   c. Determine the severity of adverse drug reactions
   d. Prioritize adverse drug reactions for further investigation

15 **CIOMS VI deals with:.............**
   a. Benefit–Risk Balance for Marketed Drugs: Evaluating Safety Signals
   b. Current Challenges in Pharmacovigilance
   c. Management of Safety Information from Clinical Trials
   d. Development Safety Update Report

16 **Schedule Y is a Part of one of the following Act:**
   a. Indian Patent Law
   b. Drugs & Cosmetic Act
   c. Drug Price Control Order
   d. The Pharmacy Act

17 **The MedDRA (Medical Dictionary for Regulatory Activities) is used for……..**
   a. Drug registration
   b. ADR coding and classification
   c. Clinical trial design
   d. Drug manufacturing standards

18 **Pharmacovigilance Programme of India started in the year**
   a. 2010
   b. 2009
   c. 2005
   d. 2012

19 **WHO-ART has...........**
   a. 4 levels hierarchical structure
   b. 10 levels hierarchical structure
   c. 5 levels hierarchical structure
   d. 6 levels hierarchical structure

20 **CIOMS stands for**
   a. Centre for International Organizations of Medical Sciences
   b. Council of International Organizations of Medical Sciences
   c. Council of International Authority of Medical Sciences
   d. Conference of International Organizations of Medical Sciences

Q. 2   Answer <u>ANY ONE</u> of the following   **12M**

    a. Give detailed account on various Active and Passive Surveillance Methods used in Pharmacovigilance.

    b. Explain in detail about history and development of pharmacovigilance program of India (PvPI)

    c. Enumerate the different types of information resources available in pharmacovigilance with drug dictionaries and coding used in pharmacovigilance.

Q. 3   Answer <u>ANY FOUR</u> of the following   **48 M**

    a. Define Adverse Drug Reactions. Classify ADR with suitable examples.

    b. What are causality assessment? What are various Do's and Don'ts for causality assessment?

    c. Explain spontaneous reporting of adverse drug reaction with suitable examples.

    d. Give a detailed account on: Vaccine Safety Surveillance

    e. Write a note on naranjo's causality assessment rule.

    f. Write short note on: a) CIOMS b) CDSCO and Pharmacovigilance
       c) MedRA

    g. Write in brief Schedule Y of Drug and cosmetics act 1945.

    h. What are the objectives of ICH guidelines? Explain periodic safety update report.

    i. What is Pharmacovigilance Programme of India? Write a note on the history of Pharmacovigilance.

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