 Final Year
Sem - VIII
02/05/2025

Duration: 3 Hrs. **Total Marks: 75**

Note: 1. All questions are compulsory.

2. Figures to the right indicate full marks.

Q.1. Choose an appropriate option for multiple choice-based questions. 20M

1. _____is the purpose of drug safety monitoring
A To verify drugs remain uncontaminated over time.
B To examine, limit, and reduce adverse treatment effects.
C To analyze and compare drug market performance.
D To support verified justification of drug promotions.

2 _____ is contraindicated during pregnancy due to its teratogenicity.
A Folic Acid
B Calcium
C Retinol
D Iron

3. _____ is the ATC code for Sumatriptan.
A As an antimigraine, code N02CC01 applies.
B As an antiviral agent, code J05AF05 applies.
C For asthma treatment, code R03AC13 applies.
D For diabetes use, code A10BB01 applies.

4 _____ is method of Pharmacovigilance.
A Induced reporting
B Online Reporting
C Sentinel Site
D Active Surveillance

5. _____system does the US FDA use for postmarket surveillance of adverse events
A Adverse Supervision and Reporting Network
B MedTrack Adverse Event Monitoring System
C FDA Adverse Event Reporting System (FAERS) for ADRs
D Global Safety and Incident Reporting Program

6. What does the term AEFI stand for?
A Accidental Error For Injection procedures in healthcare practices.
B Annual Evaluation of Immunological Framework in disease control protocols.
C Adverse Event Following Immunization, referring to post-vaccine medical occurrences.
D Advised Event For Immunologists in response to immune abnormalities.

7 The functions of UMC are_____.
A Development of Adverse Reaction Signals
B Exchange information
C Analyse Data
D Collecting, assessing and communicating information from member countries.

8. According to the principles of ICH GCP _____ is the most important consideration when conducting a clinical trial.

A Protection of trial subject
B Data Accuracy
C Quality Check
D Education and training of subject

9 The FDA launched Sentinel system in_____

A May 2010
B May 2008
C April 2010
D April 2008

10. The number of newly diagnosis cases in the specific time period called_____

A Prevalance
B ADR
C APR
D Incidence

11 _____year is known for Sulphanilamide disaster.

A 1938
B 1948
C 1958
D 1948

12 Indian Pharmacovigilance system is regulated by _____.

A USFDA
B CDSCO
C IPC
D DRDO

13 CIOMS stands for

A Council for International Organizations of Medical Sciences
B Council for Indian Organization of Medical Sciences
C Committee for International Organizations of Medical Sciences
D Council for Indian Organization of Medical Sector

14 WHO-ART has:

A 04 levels hierachial stucture
B 10 levels hierachial stucture
C 05 levels hierachial stucture
D 06 levels hierachial stucture

15 What is a key principle of good pharmacovigilance communication?

A To dismiss concerns raised by the involved parties
B To fully disclose the limits of scientific knowledge
C To promise definite solutions to pressing problems
D To rely on jargon to enhance perceived credibility

16 _____ is the Naranjo scale method of casuality assessment.

A Algorithmic Method
B Probabilistic Method
C Global Introspection
D Algebric Method

17 The E6 Guidelines of ICH is set for _____.

A Global Clinical Practice Finalized
B Studies in support of special population
C General considerations for clinical trials
D The extent of population

18. A known limitation of spontaneous ADR reporting is:_____

A Excess reporting
B False reporting
C Under reporting
D Spontaneous ADR reporting has no limitations

19 MedDRA is owned by the_____.

A ICH
B IFPMA
C WHO
D MSSO

20 The number of newly diagnosed cases in the specific time period called_____.

A Incidence
B ADR
C APR
D Prevalence

Q.2 Answer any TWO of the following **10x2=20M**

A. a. Define Causality Assessment. Write a detailed note on methods of Causality Assessment.

b. Define ADR. Describe the classification of ADRs according to severity scale.

B. a. Explain the term structure and nomenclature as per ATC classification.

b. What is daily define dose DDD, give its applications.

C. a. Elaborate Active surveillance.

b. What are the causes of AEFI.

Q.3. Answer any SEVEN of the following **5x7=35M**

A. Write the organization and objective of ICH guidelines in Pharmacovigilance.

B. Add a note on the CIOMS Working Group.

C. Explain Drug Safety Evaluation in Geriatrics Population.

D. Explain hierarchy of MedDRA.

E Explain the Goals, Roles and Responsibilities of CRO.

F. Describe Cohort Study Methods with its advantages.

G. Explain establishment of Pharmacovigilance Program.

H. What are the responsibilities of CDSCO?

I. Give a brief note on pharmacogenomics related ADR.

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