sem 8
30/9/24
PY attd

Total Marks: 75 M

Duration: 3 Hours.

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 **Guidelines for Safety Data collection are provided by _____ICH guideline**
A E18
B E16
C E19
D E17

2 **MedDRA is owned by the _____.**
A IFPMA
B ICH
C WHO
D MSSO

3 **ICSR stands for _____**
A Internal Case Study Repository form
B International Case Study Report
C Internal Case Study Report
D Individual Case Study Report

4 **J Class under ATC classification is _____.**
A Anti-infective
B Hormonal Preparation
C Anti-neoplastic agents
D Anti-parasitic agents

5 **---------- human enzyme is most abundant hepatic, which metabolizes approximately 50% of marketed drugs?**
A CYP1A1
B CYP3A4
C CYP3A
D CYP3A5

6 **FDA_____ documents and decision trees provide recommendations for medication dosing in special populations.**
A Therapeutic
B Guidance for Industry
C Special Population
D Paediatrics

7 **_____ is a process by which methyl groups are incorporated into cytosine molecules by DNMTs.**
A DNA methylation
B Chromatin Remodelling
C RNA Methylation
D Histone Modifications

8 **D & C Act was passed in**
A 1947
B 1940
C 1950
D 1980

9 **---------- is a method of communication in Pharmacovigilance.**
A None of the below
B Call
C Social Media
D Letter

10 **Management of ADR involved**
A Unwanted reactions
B Symptomatic and specific treatment of suspected reaction
C Drug Management
D Dose Reduction

11 **---------- is a type of comparative observational studies.**
A Test controlled studies
B Qualitative Studies
C Cohort Studies
D Randomized controlled trials

12 **According to the WHO Aide-memoire on Causality Assessment, which of the following is not one of the five principles underpinning the causality assessment of vaccine adverse events?**
A Strength of association
B Biological Plausibility
C Consistency
D Risk-Benefit Balance

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 **Rationalism implies all except**
A Does not need empirical proof for its conclusions
B Provides hypothesis for testing
C It is the pursuit of knowledge through reasoning
D Leads to formal truth, which may or may not be materially true

15 **Schedule Y is related to**
A Clinical Trials
B Pricing Policy of Drugs
C Pre-clinical Drug Development
D Drug Utilization Regulations

16 **What are therapeutic outcomes for patient with type 2 diabetes mellitus?**
A To keep blood glucose between 4 and 9 millimole per litre
B To prevent hypoglycaemia
C To keep blood glucose levels between 4 millimole per litre
D None of the above

17 **Temporal relationship fall under terminology section**
A Risk terminologies
B Side effect
C Drug safety concepts
D General Terminologies

18 **The sponsor in the clinical study is**
A Organisation
B Country
C Cohort
D Society

19 **Team adverse events fall under terminology section**
A Drug safety concepts
B Side effect
C Risk Terminologies
D General Terminologies

20 **Naranjo scale method of casualty Assessment is**
A Probabilistic Method
B Algorithmic Method
C Global Introspection
D Algebric Method

Q.2 Answer any <u>TWO</u> of the following 20M

A. a. Define Adverse Drug Reaction. Explain types of Adverse Drug Reaction.

b. Give reporting and management of ADR.

B. a. Explain Active Surveillance Methods. Write any two advantages and disadvantages of Active Surveillance Methods

b. Explain the principles of effective communication in Pharmacovigilance.

C. a. Write a note on ATC classifications.

J. Define Defined Daily Dose(DDD). Add a note on the limitations of Defined Daily Dose (DDD).

Q.3. Answer any SEVEN of the following 35M

A. Explain the establishment of the Pharmacovigilance Program.

B. Add a note on the Basic Drug Information Resources.

C. Write a detailed note on CIOMS working.

D. Define Causality Assessment. Write a note on different methods of Causality assessment.

E. What is the organization & objective of ICH guidelines in pharmacovigilance?

F. Explain drug safety evaluation in geriatric populations.

G. Write a note on CDSCO.

H. Describe a Cohort Study Method with its advantages.

I. Write the difference between Pre-clinical trials and Clinical Trials.