REV-01
BPH/23/28

2024/05

SET A

B. PHARM.
EIGHTH SEMESTER
PHARMACOVIGILANCE
BP805ET

[USE OMR SHEET FOR OBJECTIVE PART]

Duration : 3 hrs. **Full Marks : 75**

(PART-A: Objective)

Time : 30 min. **Marks : 20**

Choose the correct answer from the following: ***1×20=20***

1. UMC stands for
   a. Union Monitoring Centre
   b. Upper Monitoring Centre
   c. Upasala Monitoring Centre
   d. United Monitoring Centre
2. "Clinical safety data management" under which category of ICH guideline
   a. E2A
   b. E2C
   c. E2B
   d. E2D
3. ICH was established in the year
   a. 1968
   b. 2010
   c. 1999
   d. 1990
4. CIOMS established in
   a. 1949
   b. 1950
   c. 1954
   d. 1947
5. ICH consist of .....groups in pharmacovigilance
   a. 04
   b. 02
   c. 05
   d. 03
6. How many participants in GCP
   a. 8
   b. 5
   c. 7
   d. 6
7. How many core principles are there in ICH-GCP.
   a. 10
   b. 15
   c. 12
   d. 13
8. CTD stands for
   a. Common Technical Documents
   b. Control Technical Documents
   c. Common Technical Data
   d. Control Technical Data
9. How many guidelines are there in ICH for pharmacovigilance
   a. 2
   b. 4
   c. 6
   d. 8
10. UMC located in
    a. USA
    b. Sweden
    c. London
    d. Japan

11. How many members are involve in WMA?
    a. 26
    b. 150
    c. 11
    d. 14

12. WMA stands for....
    a. World Medical Association
    b. World Men Association
    c. World Medical Approval
    d. Whole Medical Association

13. CROs stand for
    a. Contract research organizations
    b. Controlled research organizations
    c. Controlled risk organizations
    d. Contract risk organizations

14. Pharmacovigilance programme of India was started by Govt of India on
    a. 14th July 2010
    b. 14th July 2020
    c. 14th July 2007
    d. 14th July 2000

15. ICH stands for
    a. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
    b. International council on harmonization
    c. Internal conference on harmonization
    d. Indian committee on harmonization

16. What is pre-term birth?
    a. Active surveillance
    b. Induced reporting
    c. Online reporting
    d. Sentinel site

17. What is the first step in management of ADR
    a. Treatment of ADR.
    b. Detection of ADR
    c. Withdraw the ADR
    d. DOSE REDUCTION

18. What is Pharmacovigilance
    a. Effects of drugs and mechanism of action
    b. Analyze the risk, safety of medicine
    c. Biochemical and physiological effect of drug
    d. Role of the drug of Genome Response

19. The functions of UMC are
    a. Development of adverse reaction signals
    b. Exchange information
    c. Analyse data
    d. Exchange data

20. The no of volunteers involved in vaccine phase I are
    a. <10
    b. 20-80.
    c. 200-300
    d. 400-1000

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PART-B :Descriptive

Time : 2 hrs. 30 min. **Marks : 35**

[Answer any seven (7) questions]

1.	Write the definition and objectives of pharmacovigilance.	5
2.	Write a note on WHO International drug monitoring program.	5
3.	Write the full form of PIDM, ICSR, ICH, CDSCO, GCP	5
4.	Write the classification of AEFI.	5
5.	What are the causes of vaccine failure and write the goals and objectives of vaccine failure	5
6.	Write the principles good pharmacovigilance communication	5
7.	Write the full name of MedDRA, DSUR, PSUR, SMQs, UNESCO	5
8.	Write the program and activities of CIOMS	5
9.	Write a note on drug safety evaluation in pregnancy and lactation.	5

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PART-C: Long type questions

[Answer any two (2) questions]

1. Write the definition of validation as per ICH, organisation, and objectives of ICH. **10**

2. Write the ADR reporting procedure in India **10**

3. Write about the communication in crisis management **10**

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