SET A

B. PHARM.
EIGHT 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. In 1948, Hannah Greener a young girl died after receiving _____
   a. Thalidomide b. Sulfanilamide elixir
   c. Chloroform d. None of the above
2. Regional pharmacovigilance center is present in
   a. 2 zone b. 4 zone
   c. 14 zone d. 8 zone
3. Anatomical Therapeutic Chemical (ATC) classification system 2nd level is
   a. Pharmacological or therapeutic group b. Clinical subgroup
   c. Chemical substances d. Anatomical group
4. Faithful adherence by patient to the prescriber's instructions is referred as
   a. Efficacy b. Causality
   c. Epidemiology d. Compliance
5. An inactive substance given to a group being studied to compare results with the effects of the active drug.
   a. Placebo b. Rechallenge
   c. Nocebo d. Dechallenged
6. The national system of reporting ADR in UK is _____
   a. Green card b. Blue card
   c. Yellow card d. Red card
7. Expedited reporting also known as
   a. Individual case report b. Rapid report
   c. Periodic safety reports d. Single case report
8. ICH was established in the year
   a. 1968 b. 2010
   c. 1999 d. 1990
9. The report which includes the information of suspected adverse drug reaction associated with administration of one or two drugs
   a. Individual case safety reports b. Individual reporting
   c. Spontaneous reporting d. Periodic safety update report
10. Pharmacovigilance planning involve
    a. Safety specification b. Pharmacovigilance method
    c. Pharmacovigilance plan d. All of the above

11. _____ should be submitted every month for first two years and annually for subsequent 2 years
    a. ICSRs
    b. ADRs
    c. PSURs
    d. None of the above

12. EudraVigilance is operated by
    a. European Economic Area
    b. European Medicines Agency
    c. European Union
    d. Uppsala Monitoring Centre

13. MedDRA is developed by
    a. ICH
    b. CIOMS
    c. CDSCO
    d. WHO

14. WHO drug code consist of _____ Characters
    a. 8
    b. 14
    c. 4
    d. 11

15. Which of the following reasons may cause vaccine failure
    a. Immunosuppression
    b. Improper brain functioning
    c. Presence of any diabetic condition
    d. Having any cardiovascular disease

16. The vaccine where a pathogen is inactivated/weakened and used in form of a vaccine to produce and immune reaction
    a. Live attenuated vaccine
    b. Recombinant vaccine
    c. m-RNA vaccine
    d. DNA vaccine

17. Poor cold chain maintenance during transportation of a vaccine leads
    a. Degradation of vaccine
    b. Pathogens becomes inactive
    c. Pathogens attacks the wfi
    d. No changes

18. A communication by consumers or healthcare professionals to a company or regulatory authority that describes one or more ADR ...
    a. Case series reporting
    b. Spontaneous reporting
    c. Stimulated reporting
    d. Direct reporting

19. A method used to encourage and facilitate reporting by health professionals for new products, or for limited period
    a. Spontaneous reporting
    b. Stimulated reporting
    c. Direct reporting
    d. Case series reporting

20. Why do communication matter in drug safety ?
    a. For the welfare of people
    b. Both "a" and "d"
    c. Only "a"
    d. To overcome extreme dangers or failures

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PART-B :Descriptive

Time : 2 hrs. 30 min. Marks : 35

[Answer any seven (7) questions]

1. Explain the Good Clinical Practices (GCP)? 5

2. Explain the method of post marketing surveillance (PMS) used by pharmaceutical industry? 5

3. Explain classification of adverse drug reaction? 5

4. Write a note on Contract Research Organisations (CROs 5

5. Write about MedDRA? 5

6. Explain pre-clinical phase data generation? 5

7. Describe about the various challenges in communication? 5

8. Write a short note on importance of communication in Pharmacovigilance. 5

9. Describe about the various causes of vaccine failure. 5

PART-C: Long type questions

[Answer any two (2) questions]

1. Discuss about anatomical, therapeutic and chemical classification of drug? **10**

2. Explain the basic drug information resources? **10**

3. Explain about the various surveillance methods of pharmacovigilance? **10**

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