

**B. PHARM.
EIGHT SEMESTER
PHARMACOVIGILANCE
BP805ET [SPECIAL REPEAT]
[USE OMR SHEET FOR OBJECTIVE PART]**

**SET
A**

Duration : 3 hrs.

Full Marks : 75

[PART-A: Objective]

Time : 30 min.

Marks : 20

Choose the correct answer from the following:

1×20=20

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

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|---|---|
| 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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