BRAINWARE UNIVERSITY

Term End Examination 2024-2025
Programme – B.Pharm-2019/B.Pharm-2021
Course Name – Pharmacovigilance
Course Code - BP805ET
(Semester VIII)

Full Marks : 75 **Time : 3:0 Hours**

[The figure in the margin indicates full marks. Candidates are required to give their answers in their own words as far as practicable.]

Group-A

(Multiple Choice Type Question) 1 x 20=20

1. *Choose the correct alternative from the following :*

(i) Identify the full form of PSUR
a) Pacific survey on user report b) Public safety update report
c) Periodic safety update report d) None

(ii) Indicate the correct one, clinical studies come under
a) Quality guidelines b) Efficacy guidelines
c) Safety guidelines d) All of these

(iii) Identify the correct way(s) of data collection_____.
a) Elicited reports b) Questionnaires
c) Spontaneous reports d) All of these

(iv) Identify the correct one, Animal studies, clinical trials, bioavailability studies are part of which application process
a) BLA b) ANDA
c) NDA d) IND

(v) Indicate the correct one, The main objective of _____ is to address the safety concern of the population.
a) ICMR b) DTAB
c) WHO d) Pharmacovigilance method

(vi) Indicate the correct one, ICH guidelines include
a) Efficacy b) Quality
c) Safety d) All of these

(vii) Choose the correct year in which sulfanilamide tragedy occurred.
a) 1838 b) 1937
c) 1951 d) 1938

(viii) Choose the appropriate one related to Phocomelia
a) Alcohol b) Thalidomide
c) Sulfa drugs d) Sulfanilade

(ix) Choose the commonly reported ADR of diuretic class of drugs

a) Alopecia
b) Skin cancer
c) Rhinitis
d) Hypokalemia

(x) Choose the appropriate full form of CDSCO

a) Central Drugs Standard Control Organization
b) Central Drugs Safety Control Office
c) Central Drugs Safety Control Organization
d) Central Directory for Safety and Control of Organization

(xi) Choose the purpose of the case report form

a) To provide a reference for all study subjects from which to analyze patient data
b) To include in the NDA filing
c) To ensure data accuracy by providing a place to store warehouse patient data for audit purposes
d) All of these

(xii) Choose the appropriate one, on which two criteria does the FDA classify NDAs

a) Novelty of the active ingredient and clinical improvement
b) Clinical improvement and effectiveness of product
c) Novelty of the active ingredient and time to market
d) Balance between safety and effectiveness

(xiii) Choose the correct one MedDRA is developed by

a) WHO-UMC
b) WHO
c) ICH
d) CDSCO

(xiv) State that the CDSCO is headed by

a) Govt of India
b) DCC
c) DCGI
d) Ministry of family and health welfare

(xv) Identify that in India ADR centers are controlled by _____

a) Govt. of India
b) WHO
c) CDSCO
d) Ministry of health and family welfare

(xvi) Identify that the ICD stands for

a) Inter Continental Diseases
b) Indian Council of Drugs
c) International Classification of Diseases
d) Indian Classification of Disease

(xvii) Identify that the nonproprietary name is also called_____.

a) Classical
b) Patent
c) Generic
d) Proper

(xviii) Select the Central drug Testing Laboratory is located at _____

a) Kasauli
b) Lucknow
c) Bangalore
d) Delhi

(xix) Select the guidelines for good manufacturing practice in India is

a) Schedule M
b) 21 CFR Part 5
c) 21 CFR Part 4
d) Schedule S

(xx) Select The headquarter of the WTO is located at _____

a) Czech
b) Austria
c) Geneva
d) Belgium

Group-B

(Short Answer Type Questions) 5 x 7=35

2. Define and classify ADR. (5)
3. Explain in detail about stimulated reporting in pharmacovigilance. (5)
4. Compare pharmacogenetics and pharmacogenomics. (5)
5. Explain in detail about communication with regulatory agencies and the media. (5)
6. Explain genetic polymorphism of drug transporters and mutation of drug metabolizers. (5)

7. Explain in detail about safety of vaccine pharmacovigilance. (5)

OR

Explain in detail the case-control study and the cohort study. (5)

8. Explain the documentation for adverse drug reactions. (5)

OR

Explain in detail about communication in drug safety crisis management. (5)

Group-C

(Long Answer Type Questions) 10 x 2=20

9. Describe in detail the ICSR. (10)
10. Explain in detail about the contact research organization. (10)

OR

Explain in detail about drug event monitoring and registries. (10)

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