BRAINWARE UNIVERSITY

Term End Examination 2023-2024
Programme – B.Pharm-2019/B.Pharm-2020
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) Select the one is not related to the ADR type A

a) It is predictable b) It occurs due to genetic
c) It is pharmacodynamic effect d) It is dose related

(ii) Select the one that is not related to pharmacovigilance

a) ADR b) Grating license for production
c) Product quality d) Medication occurs

(iii) Select the correct one, _____ is defined unintended effects occurring at normal dose of medication.

a) Side effects b) Adverse event
c) ADR d) None

(iv) Select the part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use

a) Drug master file b) Gap analysis
c) Inter company transfer d) Good manufacturing practices

(v) Identify the full form of ICSR

a) WHO-UMC b) Indian council for survey and reports
c) International council for safety reports d) Individual case safety reports

(vi) Identify the full form of PSUR

a) Pacific survey on user report b) Public safety update report
c) Periodic safety update report d) None

(vii) Identify the full form of CTD

a) Common technical department b) Council of technical department
c) Common technical document d) Computer tomographic design

(viii) Identify the correct way(s) of data collection_____.

a) Elicited reports b) Questionnaires
c) Spontaneous reports d) All of these

(ix) Indicate the factors influencing the susceptibility to adverse reaction to pediatric populations

a) Low metabolizing capacity
b) Accumulation of drug
c) Immature organ system
d) All of these

(x) Indicate the number of groups working in CIOMS.

a) 13
b) 8
c) 4
d) 12

(xi) Identify the oldest quality control laboratory of the Drug Control Authorities in India.

a) Central Drugs Testing Laboratory, Hyderabad, AP
b) Central Drugs Testing Laboratory, Mumbai
c) Central Drugs Testing Laboratory, Chennai, Tamil Nadu
d) Central Drugs Testing Laboratory, Kolkata

(xii) Identify the appropriate full form of UMC

a) Uppsala Monitoring Council
b) Uppsala Monitoring Center
c) United Medical Council
d) Unique Method Of Consert

(xiii) Choose the appropriate one related to Phocomelia

a) Alcohol
b) Thalidomide
c) Sulfa drugs
d) Sulfanilade

(xiv) Choose the appropriate full form of AMC

a) Allopathic motion center
b) ADR Monitoring Center
c) Alternative Medical Council
d) Ayurvedic Monitoring conference

(xv) Choose the appropriate full form of DTC

a) Drug and Therapeutic Committee
b) Drug and Therapeutic Council
c) Dose and time curve(
d) Drug and Technical Committee

(xvi) Choose the appropriate full form of NCC is

a) National coordinating centers
b) National communication centers
c) National credit council
d) National coordinating council

(xvii) Choose the correct vitamin is avoided during pregnancy

a) A
b) D
c) C
d) E

(xviii) State that the CDSCO is headed by

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

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

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

(xx) Select the copyrights is granted for

a) Logo
b) Music and Literature
c) Radio isotopes
d) Pharmaceutical product

Group-B

(Short Answer Type Questions) 5 x 7=35

2. Describe the origins and progression of pharmacovigilance. (5)
3. Explain the organization and objective of ICH. (5)

4. Write down in detail the CIOMS form. (5)
5. Explain CRO's and the importance of CRO's in the national program. (5)
6. Explain the inclusion and exclusion criteria involved in a clinical trial. (5)
7. Explain the documentation for adverse drug reactions. (5)

OR

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

8. Explain in detail about comparative observational studies. (5)

OR

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

Group-C

(Long Answer Type Questions) 10 x 2=20

9. Explain in brief the classifications of ADR and ADE. (10)

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

OR

Explain in detail about targeted clinical investigations. (10)

****