BRAINWARE UNIVERSITY

Term End Examination 2023
Programme – B.Pharm-2019
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 correct one, an IRB is also known as _____
   a) ICH b) IEC
   c) DTAB d) FDA

(ii) Indicate the correct one, In vitro study perform in or on _____
   a) Human b) Animal
   c) Living cells d) Test tube

(iii) State the year in which Sulfanilamide tragedy occurred
   a) 1838 b) 1937
   c) 1951 d) 1938

(iv) Choose the appropriate full form of AMC
   a) Allopathic motion center b) ADR Monitoring Center
   c) Alternative Medical Council d) Ayurvedic Monitoring conference

(v) Choose the commonly reported ADR of diuretic class of drugs
   a) Alopecia b) Skin cancer
   c) Rhinitis d) Hypokalemia

(vi) Choose that happens to the case report forms (CRFs)
   a) The CRF data is compiled and submitted to Regulatory Affairs b) The CRF data is compiled and submitted to the FDA in the IND
   c) The CRF data is aggregated by an external party if the trial was double blinded to assess the drug\'s safety and efficacy d) The CRF data is aggregated and analyzed to assess the drug\'s safety and efficacy

(vii) Choose the appropriate full form of ICH is
   a) Intermittent conference on harmonization b) Intermittent council on harmonization
   c) International conference on harmonization d) International council on harmonization

(viii) choose the correct one in Pharmacovigilance activities, especially in preparation for the early post-marketing period of a new drug is known as _____planning.

a) ABC
b) A2C
c) E2E Pharmacovigilance
d) None

(ix) Choose the schedule _____ is defined as the requirements and guidelines for permission to import and manufacture new drugs for sale or for clinical trials.

a) Y
b) M
c) T
d) A

(x) Identify that the authorized advisory committee of Indian Govt. pertaining to Drug and Cosmetic act, is known as

a) DTAB
b) IPC
c) CDSCO
d) None

(xi) 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

(xii) Identify that the ATC stands for :

a) American Technical Council
b) Anatomical Therapeutic Chemical Classification
c) Anatomical Theoretical Classification
d) Anatomical Therapeutic committee

(xiii) Select the one is not related to Type B reaction

a) Anaphylaxis
b) Dose
c) Drug allergy
d) Idiosyncrasy

(xiv) Select the correct one, An _____ is any untoward medical occurrence in a patient administered a medicinal product and which does not necessarily have a casual relationship with this treatment.

a) Adverse event
b) Adverse event
c) Idiosyncrasy
d) None

(xv) 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

(xvi) 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

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

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

(xviii) Identify the name of the study of all gene variants/polymorphisms that influence patient response to given drug is known as _____.

a) Pharmacodynamic
b) Pharmacogenomics
c) Pharmacokinetics
d) Pharmacogenetics

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

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

(xx) Identify the correct one, Animal studies, clinical trials, bioavailability studies are part of which application process

a) BLA
b) ANDA
c) NDA
d) IND

Group-B

(Short Answer Type Questions) 5 x 7=35

2. Describe the safety Monitoring of Medicines (5)
3. Explain MedDRA and its standard queries. (5)
4. Explain CRO's and the importance of CRO's in the national program (5)
5. Describe specialized resources for ADRs (5)
6. Explain in detail about comparative observational studies (5)
7. State the importance of communication with Regulatory agencies and Business partners. (5)

OR

Write the importance of communication in pharmacovigilance. (5)

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

OR

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

Group-C

(Long Answer Type Questions) 10 x 2=20

9. compare ADR and ADE (10)
10. Explain in detail about Contact Research Organization. (10)

OR

Explain in detail about Drug Event Monitoring and registries (10)

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