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) Indicate the correct one, Inspection is a part of the _____
   a) Quality planning
   b) Quality assurance and quality control
   c) Quality circle
   d) Quality improvement

(ii) Indicate the correct one, Stability testing comes under
   a) Quality guidelines
   b) Efficacy guidelines
   c) Safety guidelines
   d) All of these

(iii) Identify the appropriate full form of UMC
   a) Uppsala Monitoring Council
   b) Uppsala Monitoring Center
   c) United Medical Council
   d) Unique Method Of Consert

(iv) Choose the appropriate full form of PvPI
   a) Pharmacovigilance Point of India
   b) Pharmacovigilance Program of India
   c) International Program of Pharmacovigilance
   d) None

(v) Memorize the number of volunteers involved in phase I are -
   a) 220-380
   b) 100-180
   c) 120-280
   d) 20-80

(vi) Choose the appropriate full form of GPP
   a) Good Pharma Product
   b) Good Pharmacovigilance Practice
   c) Good Pharmacy Practice
   d) Guidelines for Pharmaceutical Product

(vii) Choose the appropriate full form of NCC is
   a) National coordinating centers
   b) National communication centers
   c) National credit council
   d) National coordinating council

(viii) Choose the study leaders based at each site during the clinical trial
   a) Chief medical officer and clinical research associates
   b) Principal investigators and clinical research associates
   c) Study coordinates and chief medical officer
   d) Principal investigators and study coordinates

(ix) Select what is pre-term birth?

a) less than 37 completed
b) less than 27 completed
c) less than 17 completed
d) less than 47 completed

(x) Choose the appropriate one, the primary focus of Phase 3 Clinical testing

a) How to manage costs
b) The optimal range of effective dosage
c) The analysis of data results from the small-subset target population
d) The collection and analysis of highly specific efficacy end-point data

(xi) Choose the MedDRA and DILI are the recent working groups for which organization?

a) ICMR
b) CDSCO
c) CIOMS
d) WHO

(xii) Identify that the correct age group for pediatric patients?

a) From birth to 19 years
b) From birth to 18 years
c) 1-6 years
d) None

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

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

(xiv) Identify that the Schedule P is known as _____.

a) Packaging of drugs
b) Colour pigments
c) Provisional application
d) Life period of drugs

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

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

(xvi) Identify that the ATC stands for :

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

(xvii) Identify that the Full form of CFR is----------

a) Civil federal rules
b) Code of federal rules
c) Code of federal regulations
d) Civil federal regulations

(xviii) Identify that the as per ATC, drugs are classified into_____levels.

a) 14
b) 10
c) 5
d) 4

(xix) Identify that the Drug regulatory agency of country Australia-----

a) MHRA
b) ANVISA
c) MCC
d) TGA

(xx) Select the guideline ICH Q1A (R2) refers to

a) Impurities
b) Stability study of new molecular entities and associated drug products
c) Generation of photostability information
d) Analytical validation

Group-B

(Short Answer Type Questions) 5 x 7=35

2. Write down about CIOMS form. (5)
3. Represent schedule Y in detail. (5)
4. Define and classify ADR (5)
5. Distinguish between Inclusion and Exclusion Criteria (5)
6. Explain in detail the case-control study and cohort study (5)
7. Explain in detail about Vaccine Pharmacovigilance (5)

OR

Explain in detail about communication with regulatory agencies and media (5)

8. Explain CRO's and the importance of CRO's in the national program (5)

OR

Write the importance of communication in pharmacovigilance. (5)

Group-C

(Long Answer Type Questions) 10 x 2=20

9. Explain GCP in Pharmacovigilance studies. (10)
10. Explain in detail vaccine failure in pharmacovigilance (10)

OR

Explain in detail about Contact Research Organization. (10)

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