



22426-41079



Library
Pharmaceutical Technology
Brainware University
Barasat, Kolkata-700125

BRAINWARE UNIVERSITY

Term End Examination 2025-2026
Programme – B.Pharm-2021/B.Pharm-2022
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 ICSR
 - a) WHO-UMC
 - b) Indian council for survey and reports
 - c) International council for safety reports
 - d) Individual case safety reports
- (ii) Identify the full form of PSUR
 - a) Pacific survey on user report
 - b) Public safety update report
 - c) Periodic safety update report
 - d) None
- (iii) Identify the full form of CTD
 - a) Common technical department
 - b) Council of technical department
 - c) Common technical document
 - d) Computer tomographic design
- (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) Identify the full form of GCP
 - a) General Conference on Pharmacy
 - b) Good Clinical Practice
 - c) Geneva Conference on Pharmacovigilance
 - d) None
- (vi) Identify the full form of IRB
 - a) International Reserve Bank
 - b) Institutional Recruitment Board
 - c) International Research Board
 - d) Institutional Review Board
- (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 appropriate full form of IND is
 - a) Imperial New Dossier
 - b) Imperial New Drug
 - c) Investigational New Drug
 - d) Investigational New Dossier

- (ix) Choose the appropriate full form of ADR
- Absolute Dose Reaction
 - Absolute Dose Reaction
 - Adverse Drug Reaction
 - Adverse Dose Reaction
- (x) Choose the appropriate, ICH secretariat is based in.....
- Zurich
 - Austria
 - Geneva
 - India
- (xi) State that the CDSCO is headed by
- Govt of India
 - DCC
 - DCGI
 - Ministry of family and health welfare
- (xii) Select the Central drug Testing Laboratory is located at _____
- Kasauli
 - Lucknow
 - Bangalore
 - Delhi
- (xiii) Select the guidelines for good manufacturing practice in India is
- Schedule M
 - 21 CFR Part 5
 - 21 CFR Part 4
 - Schedule S
- (xiv) Select The headquarter of the WTO is located at _____
- Czech
 - Austria
 - Geneva
 - Belgium
- (xv) Choose which option is not related to subunit vaccine.
- Protein based vaccine
 - Polysaccharide vaccine
 - Live vaccine
 - Conjugated vaccine
- (xvi) Memorize the number of volunteers involved in phase I are -
- 220-380
 - 100-180
 - 120-280
 - 20-80
- (xvii) Predict who is responsible for WHO international drug monitoring Programme?
- Japan
 - FDA
 - EU
 - Uppsala Monitoring Center
- (xviii) Recall the statement Indian Pharmacovigilance system is regulated by -
- CDL
 - USFDA
 - CDSCO
 - CFR
- (xix) Memorize the 1st edition of Indian Pharmacopoeia was published in the year
- 1920
 - 1950
 - 1955
 - 1900
- (xx) Memorize which one is a Pharmacovigilance Software mostly used for API products.
- Oracle Argus Safety
 - EDC
 - CTMS
 - RTSM

Library
Pharmaceutical Technology
Brainware University
Barasat, Kolkata-700125

Group-B
 (Short Answer Type Questions)

5 x 7=35

- Describe in detail about PvPI. (5)
- Explain the daily defined dose. (5)
- Explain MedDRA and its standard queries. (5)
- Explain the inclusion and exclusion criteria involved in a clinical trial. (5)
- Explain the documentation for adverse drug reactions. (5)
- Explain the communications in pharmacovigilance. (5)

OR

- Explain in detail about safety of vaccine pharmacovigilance. (5)
- Explain in detail about communication in drug safety crisis management. (5)

OR

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

Group-C
(Long Answer Type Questions)

10 x 2=20

9. Explain in detail about active and passive surveillance. (10)
10. Explain in detail about drug event monitoring and registries. (10)

OR

Explain in detail about targeted clinical investigations. (10)

Library
Pharmaceutical Technology
Brainware University
Barasat, Kolkata-700125