

**Manipal College of Pharmaceutical Sciences**  
**Manipal Academy of Higher Education, Manipal**  
**BPharm Semester VIII - End Semester Examination – July 2021**  
**PPR-BP805ET: PHARMACOVIGILANCE**

Date: 09-07-2021

Duration: 2:30pm to 4:30pm

Max. Marks: 50

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**Multiple Choice Questions**

1. The headquarters of World Health Organization (WHO) Programme for International Adverse Drug Monitoring is at -----
  - A. New Zealand
  - B. Sweden
  - C. Switzerland
  - D. USA
  
2. Which of the following scale is not used for the causality assessment of adverse drug reactions?
  - A. French imputation method
  - B. Karch and Lasagna's
  - C. Modified Hartwig and Seigel
  - D. Naranjo scale
  
3. Incidence adverse drug reaction (ADR) more than 10 percent is called -----
  - A. Common ADR
  - B. Rare ADR
  - C. Very common ADR
  - D. Very rare ADR
  
4. Response of adverse reaction upon cessation of drug is referred as -----response
  - A. Dechallenge
  - B. Probable
  - C. Rechallenge
  - D. Unlikely
  
5. USFDA maintains a voluntary ADR reporting system through its -----programme
  - A. MedWatch
  - B. MHRA
  - C. Vigibase
  - D. Vigiflow
  
6. The main use of ATC system is for
  - A. Better marketing decisions
  - B. Drug utilization studies
  - C. Identifying counterfeit drug
  - D. Regulatory approval of drugs

7. To make INN universally available, they are formally placed by ----- in public domain
  - A. IUPAC
  - B. UMC
  - C. USFDA
  - D. WHO
  
8. In Eudravigilance, the reaction monitoring report is used for -----
  - A. Clinical Trail reports
  - B. Multi-Axial terminology
  - C. Regulatory reports
  - D. Signal Detection
  
9. ----- aims to detect adverse events early to trigger accurate risk assessment and appropriate response (risk-management) to the problem
  - A. Adverse drug reactions
  - B. Drug Interactions
  - C. Hemovigilance
  - D. Vaccine pharmacovigilance
  
10. Communication is a part of ----- skills
  - A. Hard
  - B. Rough
  - C. Short
  - D. Soft
  
11. Role of Case reports is to -----
  - A. describe a new pathogen
  - B. describe presentation of disease
  - C. recognize common manifestation of a known disease
  - D. recognize known adverse reaction of a drug
  
12. Following is an active surveillance method for adverse drug reaction monitoring
  - A. Case series
  - B. Drug event monitoring
  - C. Spontaneous reports
  - D. Stimulated reporting
  
13. Pharmacovigilance documents intended to provide an evaluation of the risk-benefit balance of a medicinal product at defined time points after its authorization.
  - A. Expedited reports
  - B. Individual case safety reports
  - C. Periodic safety update report
  - D. Spontaneous report

14. ----- help researchers to learn more about the treatment and doing a service to future patients.
- A. Phase I studies
  - B. Phase II studies
  - C. Phase III studies
  - D. Phase IV studies
15. The enzyme that metabolizes most of the medicines is -----
- A. CYP1A2
  - B. CYP2C19
  - C. CYP2C9
  - D. CYP2D6
16. ----- test will identify the vulnerable patients to hemolysis with certain drugs.
- A. DPD deficiency
  - B. G6PD deficiency
  - C. HLA-B variants
  - D. UGT1A1 variants
17. Beers Criteria is
- A. potentially appropriate medications to avoid in older adults with certain conditions
  - B. potentially appropriate medications to avoid in pediatrics with certain conditions
  - C. potentially inappropriate medications to avoid in older adults with certain conditions
  - D. potentially inappropriate medications to avoid in pediatrics with certain conditions
18. Which one of the drug is an example for pregnancy category X?
- A. Gentamicin
  - B. Losartan
  - C. Metformin
  - D. Methotrexate
19. The clinical trial and new drug development in India are explained in -----
- A. Schedule H
  - B. Schedule M
  - C. Schedule X
  - D. Schedule Y
20. In general, polypharmacy has been defined as -----
- A. a single patient taking more than five drugs daily
  - B. multiple medications prescribed to manage the same disease
  - C. multiple medications taken to manage comorbid conditions
  - D. the prescription of two drugs that may interact to result in adverse effects

### Short Answer Questions

6x5 Marks

- 1 Explain the Hartwig's severity assessment of adverse drug reactions. 5 Marks
- 2 Describe the structure of ATC system and explain the purpose of ATC/DDD system. 5 Marks
- 3 Discuss establishment of pharmacovigilance program in a hospital. 5 Marks
- 4 Explain the importance of effective communication in pharmacovigilance with its challenges. 5 Marks
- 5 Write the ICH standards for individual case safety reports (ICSRs). 5 Marks
- 6 Discuss single dose toxicity studies in schedule Y. 5 Marks