Seat No: _____ Enrollment No: _____

# PARUL UNIVERSITY

## FACULTY OF PHARMACY

### B. Pharm. Summer 2022 - 23 Examination

**Semester: 8** **Date: 17/04/2022**
**Subject Code: BP805ET** **Time: 10:00am to 1:00pm**
**Subject Name: Pharmacovigilance** **Total Marks: 75**

Instructions:
1. Figures to the right indicate maximum marks.
2. Make suitable assumptions wherever necessary.

**Q.1 Multiple Choice Questions (MCQs) (1 Mark Each)** **(20)**

1. Pharmacovigilance Continue throughout:-
   a) Post marketing surveillance b) Pre & post marketing surveillance
   c) Pre marketing surveillance d) None of the above
2. Pharmacovigilance Programme of India started in,
   a) 2009 b) 2010
   c) 2005 d) 2012
3. Serious Adverse Event
   a) Result in death b) Life threatening
   c) Disability d) All of the above
4. Type I ADR reactions is_____
   a) Caused when T-cells bind to a specific antigen b) caused by tissue injury
   c) IgE mediated d) Caused by cytotoxic antibodies
5. The incidence ADR is highest in _____.
   a) Children b) Elderly
   c) Women d) Men
6. Which of the following reaction is called Augmented adverse drug reactions?
   a) Genetically determined effects b) Idiosyncrasy.
   c) Rebound effect on discontinuation d) Allergic reactions & anaphylaxis.
7. Idiosyncrasy is_____.
   a) Type A ADRs b) Type B ADRs
   c) Type C ADRs d) Type D ADRs
8. Which of the following terms does not describe an Adverse Drug Reaction?
   a) Idiosyncrasy b) Anaphylaxis
   c) Teratogenic effect d) Placebo effect
9. Which of the following adverse drug reactions would you report to the Medicines and Healthcare Products regulatory Agency (MHRA) via the yellow card system for reporting?
   a) A patient reports a skin rash after starting a course on amoxicillin capsules. b) A patient report experiencing dyspepsia when they take their indomethacin capsules.
   c) A patient complains of a dry irritating cough since they have started taking ramipril. d) A patient complains they have experienced diarrhea since taking azilsartan.
10. Pharmacovigilance is done for monitoring of
    a) Drug price b) Unethical practices
    c) Drug safety d) Pharmacology of drug
11. Which of the following is Type B ADRS?
    a) Hypoglycemia caused by Insulin b) Dryness of mouth caused by Atropine
    c) Anemia in patient with G6PD deficiency caused by Primaquine d) Hyperglycemia caused by thiazide diuretics
12. According to Rawlins–Thompson classification Type D ADR includes_____
    a) Carcinogenesis b) Bradycardia associated with beta blockers
    c) Anaphylaxis associated with penicillin d) Opiate withdrawal syndrome

13. _____ is an example of latent adverse drug reactions.
    a) Antibiotic-associated diarrhea
    b) Tardive dyskinesia
    c) Serum sickness
    d) Severe bronchoconstriction
14. Which one of these is a genetically determined adverse drug reactions?
    a) Addiction
    b) Teratogenicity
    c) Carcinogenicity
    d) Idiosyncrasy
15. What Is the Difference Between An ADE And ADR?
    a) There may not be a causal relationship between a drug and an ADE, whereas, there is a causal link between a drug and an adverse drug reaction.
    b) There may be a causal relationship between a drug and an ADE, whereas, there is a causal link between a drug and an adverse drug reaction.
    c) There may not be a causal relationship between a drug and an ADE, whereas, there is not a causal link between a drug and an adverse drug reaction.
    d) There may not be a causal relationship between a drug and an ADE, whereas, there is a causal link between a drug and an adverse drug event.
16. What Do You Mean By Meddra?
    a) Medical Data for Regulatory Activities.
    b) Medical Dictionary for Regulatory Actions.
    c) Medical Dictionary for Right Activities.
    d) Medical Dictionary for Regulatory Activities.
17. Name The Regulatory Bodies In Japan ?
    a) European Medicines Agency (EMEA).
    b) USFDA
    c) Ministry of Health, Labour and Welfare (MHLW).
    d) CDSCO
18. Which of the following software's Not used in pharmacovigilance is:
    a)Oracle Argus Safety
    b) PvNET
    c) Argus
    d)DigSMap
19. What is ICSR reporting?
    a) Individual Co-Case Safety Report
    b) Individual Case Safety rate
    c) Individual Case Safety Report
    d) Individual Case Study Report
20. International database called _____.
    a) VigiBase.
    b)WHO
    c) Uppsala Monitoring Centre
    d)ICH

**Q.2 Long Answers (any 2 out of 3) (10 Mark Each)** **(20)**

1. Write a short note on Pharmacovigilance Program of India (PvPI)
2. Define ADR and ADE and describe any one causality assessment methods.
3. Describe in detail: ATC, DDD and ICD.

**Q.3 Short Answers (any 7 out of 9) (5 Mark Each)** **(35)**

1. Write the regulatory requirement in Indian and global pharmacovigilance.
2. Describe the Pharmacovigilance in terms to Pregnancy and lactation.
3. Write ICH Guidelines for Pharmacovigilance in brief.
4. Describe the process of ADR reporting in India.
5. Write a note on AEFI.
6. Describe MedDRA and coding in pharmacovigilance.
7. Write active and passive surveillance method of reporting in Pharmacovigilance.
8. Explain case control and cohort study with suitable example.
9. Write a note on communication in Pharmacovigilance.