**PHARMACOVIGILANCE**

 **Long Essays**

1. Define pharmacovigilance. Discuss in detail reporting and management of ADRs along with causality assessment scales
2. Discuss in detail setting up of a pharmacovigilance system in hospital
3. What do you meant by Vaccine Pharmacovigilance. Discuss in detail Passive and active surveillance for vaccine safety study
4. Define Adverse Drug Reactions. Classify ADRs with suitable examples. Explain the mechanism of Type-B adverse drug reactions
5. Explain in detail comparative observational researches as tools for vaccine safety studies
6. Discuss in detail establishment and operation of drug safety department in pharmaceutical industry.
7. Define ADR. Discuss in detail about the detection and reporting of ADR
8. Discuss in detail about spontaneous case reports and case series
9. Explain the drug information sources and give the specialized resources or ADR
10. Enumerate the different method of causality and severity assessment of ADR and explain the WHO scale
11. Explain the establishing pharmacovigilance program in the hospital
12. Discuss in details of passive surveillance and active surveillance. Explain the drug event monitoring program
13. Discuss the causality assessment of ADR. Explain Narinjo scale
14. Discuss in detail of Cohort and case control study
15. Explain the applications of MedDRA and standard MedDra queries
16. Discuss in detail basic and specialized drug information resources in pharmacovigilance
17. What is Vaccine safety surveillance? Explain in detail different types of pharmacovigilance methods used for passive and active surveillance.
18. Define adverse drug reactions. Discuss in detail causality, severity and seriousness assessment of ADRs
19. Discuss in details vaccine safety surveillance
20. Define Pharmacovigilance. Discuss the role of Pharmacist in detection,reporting and management of ADRs in hospital
21. Explain in detail MedDRA and WHO-AR
22. What are the objectives of pharmacovigilance programme of India. .Explain in details various methods of monitoring,detecting and reporting of ADRs
23. Discuss various factors to be considered for setting up Pharmacovigilancecentre in industry and in hospital
24. Explain in details spontaneous case reports and case series as pharmacovigilance methods for vaccine safety surveillance.
25. Explain scope of pharmacovigilance and methods of ADR reporting in India
26. Discuss in detail setting up of a drug safety department in Industry
27. What do you meant byVaccinePharmacovigilance..Compare and contrast various observational methods for vaccine safety study.

**Short Essays ( 5 marks)**

1. Discuss in details preventability assessment of ADRs
2. Estabilishing National pharmacovigilanceprogramme
3. Scope of MedDRA and Clinical research organization
4. Advantages and disadvantages of case control studies in vaccine safety evaluation
5. Discuss in details clinical trials for drug safety data generation
6. Write a note on Good clinical practice in pharmacovigilance studies
7. Mention the importance aspects of ICH guidelines for expedited reporting
8. Drug safety evaluation in geriatric and pediatric populations
9. Discuss Naranjo’S and WHO causality assessment scales
10. Idiosyncratic and hypersensitivity reaction What are the basic guidelines for coding as per ICD-10 system
11. Define vaccine. Explain reasons for vaccination failure
12. Explain Pre- marketing and Post marketing clinical trials.
13. Role of Pharmacist in management of ADRs
14. Write a note on clinical trial regulations in India
15. Explain predisposing factors of adverse drug reactions
16. Write a note on ATC classification of drugs
17. How will you investigate AEFI
18. Role o CDSCO in pharmacovigilance
19. Write a note on post approval expedited reporting
20. Write a note on pharmacovigilance of India(PvPI)
21. What are the prerequisite for setting up pharmacovigilancecentre in a hospital
22. Write a note on risk benefit assessment of vaccine
23. Writ a note on post approval expedited reporting
24. Describe organization and objective of ICH
25. Writ a note on Schedule Y
26. What are the requirements of ICSR
27. What is periodic safety update reports
28. Discuss in detail mechanisms of type A adverse drug reactions
29. GCP-ICH guidelines
30. Write a note on targeted clinical investigations
31. What are the factors to be considered for the drug safety evaluation in Geriatrics
32. Write a note on Cross-sectional study
33. Discuss in detail drug safety evaluation in pregnant and lactating women
34. what are the requirements of individual case safety reports
35. Discuss in detail WHO drug dictionary and coding in pharmacovigilance
36. Explain periodic safety update reports (PSURs)Importance of safety monitoring of drug
37. Severity assessment of ADR
38. Establishing national pharmacovigilance program
39. Operation of drug safety department in industry
40. ATC classification of drugs
41. Give the different types ADE on vaccine
42. Explain safety data generation
43. Functions of CDSCO in pharmacovigilance
44. Write a note on drug safety evaluation in paediatric population
45. Write a note on GCP guidelines in pharmacovigilance
46. Define and classify Adverse drug reactions
47. Discuss the importance of effective communication in Pharmacovigilance
48. Write a note on international classifications of diseases
49. Discuss briefly preclinical phase of safety data generation
50. What are the specialized drug information resources for ADRs
51. Explain individual case study reports(ICSR)
52. Importance of safety monitoring of Medicines
53. Explain briefly Schedule Y of D&C Act
54. Write a note on Expedited reporting and post approval expedited reporting
55. Discuss various methods used to detect and monitor ADRs with its merits and demerits
56. How will you communicating vaccine safety issues with healthcare facilities and Media
57. Write a note on Med DRA
58. Discuss in detail post approval phase of drug safety data generation
59. What are the basic drug information resources for ADRs
60. Organization and functions of ICH
61. Discuss briefly scales used for predictability and preventability assessment of ADRs
62. Describe briefly on WHO international drug monitoring program
63. Explain the predictability and preventability of ADR
64. Explain the adverse event following immunization
65. Write a note on Post approval phase
66. Mention the role of contract research organization
67. Write a note on periodic safety reports
68. Describe standard Med DRA queries
69. Describe the drug safety evaluation in Geriatrics
70. Write a note on ICH
71. Describe Safety monitoring of medicine
72. Describe international classification of disease
73. Describe briefly on good clinical practice in pharmacovigilance study
74. Individual case safety reports
75. Describe organization and objective of ICH
76. Short note on functions of contract research organization
77. Explain CIOMS requirements for ADR reporting
78. Explain immunization safety surveillance system
79. Write a note on predictable ADR

**Short Answers (**2 marks)

1. Different software used in ADR
2. Define PvPI
3. What is Drug event monitoring
4. Give the application of Defined daily dose in pharmacovigilance
5. Prescription event monitoring
6. Requirements for CIOMS form
7. Reporting ADR
8. Importance of vaccine safety
9. What is preclinical phase
10. Vaccination failure
11. Give examples of ADRs due to genetic defect in distribution
12. What are the factors to be considered while evaluating drug safety in Geratrics
13. Eudravigilance
14. List out applications of causality assessment
15. Mention the levels of ATC
16. Targeted clinical investigations
17. Reasons for vaccine failures
18. What is AEFI ?
19. Objectives of ICH
20. Mention few primary sources of drug information
21. Importance of Pharmacogenomics
22. Sentinel sites as active surveillance
23. What is teratogenicity .Give examples
24. What is phase II of clinical trials
25. Mention few predictable adverse drug reactions
26. Genetically determined toxicities
27. VSD
28. Advantages and disadvantages of passive surveillance vaccine safety
29. Importance of post approval expedited reporting
30. ICH guidelines for pharmacovigilance planning
31. Goals of CDSCO(India)
32. Genetic related ADRs with examples
33. Databases for pharmacovigilance study
34. What is PSUR and DSUR
35. What is primary purpose of ICH?
36. List few drugs causing teratogenicity ?
37. What do you meant by Dechallenge and rechallenge
38. List out types of products in WHO-drug dictionary
39. List out steps involved in vaccine pharmacovigilance
40. Advantages Case series for vaccine safety study
41. What are the limitations of pre clinical phases
42. What are the objectives of ICH
43. What is post marketing safety?
44. Organization of ICH
45. List out the role of CDSCO(India) and CIOMS
46. What is pharmacogenomics?
47. What is CIOMS form
48. Write a note on Vaccine safety datalink
49. Coding for ADR
50. Define Vigiflow, WHO-ADR, ADEWhat is AEFI ?
51. Mention the objectives of ICH
52. Genetic polymorphism
53. Define Pharmacogenomics
54. Sentinel sites
55. Classify ADRs according to severity
56. Importance of using standard dictionary
57. List out factors affecting adverse effects of vaccine
58. Define safety surveillance
59. Spontaneous case reports
60. What are the minimum criteria required for a valid Report?
61. What are the three minimum GCP principals
62. Responsibilities of CDSCO(Indian)
63. Give examples of Pharmacokinteic ADRs
64. List four drugs contraindicated in pregnant and lactating women
65. What is teratogenicity and idiosyncrasy
66. What is phase IV of clinical trials
67. Defined daily doses
68. Genetically determined toxicities
69. VSD
70. Factors affecting AEFI surveillance
71. What is CIOMS working groups
72. What are the main guidelines of ICH
73. Give two examples of ADRs due to genetic defect in metabolism
74. VERS
75. Safety Signals
76. What is phase .III of clinical trials
77. How will you calculate DDD?
78. Objectives of CDSCO(India)
79. Stimulated reporting
80. Classification of ADR
81. Defined daily doses
82. Write a note on Sentinel sites
83. Role of CDSCO
84. Vaccination failure
85. Factors affecting immunization safety
86. Individual case safety reports
87. Give two example for Genetics related ADR
88. Write a note on volunteers involved in clinical phases
89. Short note on CIOMS form
90. Write a note on anaphylactic reaction
91. Write a note on Probable, Predictable
92. Drug safety crisis management
93. Give the importance of VARES
94. Cross sectional studies
95. Periodic safety update reports
96. Classification of ADE
97. Drug safety on geriatrics
98. Define pharmacogenomics
99. Write a note on Eudravigilance