BRAINWARE UNIVERSITY

Term End Examination 2021 - 22
Programme – Bachelor of Pharmacy
Course Name – Pharmacovigilance
Course Code - BP805ET
(Semester VIII)

Time allotted : 1 Hrs.30 Min. **Full Marks : 75**

[The figure in the margin indicates full marks.]

Group-A

(Multiple Choice Type Question) 1 x 75=75

Choose the correct alternative from the following :

(1) Which of the following is not related to the ADR type A?
a) It is predictable
b) It is dose related
c) It is pharmacodynamic effect
d) It occurs due to genetic

(2) Sulfanilamide tragedy occurred in the year
a) 1938
b) 1937
c) 1951
d) 1838

(3) Phocomelia related to
a) Sulfanilade
b) Sulfa drugs
c) Alcohol
d) Thalidomide

(4) PvPI stands for
a) Pharmacovigilance Power of India
b) Pharmacovigilance Program of India
c) International Program of Pharmacovigilance
d) None

(5) Which of the following is not related to Type D reaction?
a) Accumulation of drug
b) Chemotherapy secondary tumor
c) Analgesic nephropathy
d) Anaphylaxis

(6) Type I ADR reaction is caused
a) IgE mediated
b) By tissue injury
c) When T cell bind to a specific antigen
d) By cytotoxic antibodies

(7) Idiosyncarsy is related to
a) Anaphylaxis
b) Genetically determined effects
c) Allergic reaction
d) Cytotoxic antibodies

(8) GPP stands for

a) Good Pharmacovigilance Practice
b) Good Pharmacy Practice
c) Good Pharma Product
d) Guidelines for Pharmaceutical Product

(9) _____ is defined unintended effects occurring at normal dose of medication.

a) ADR
b) Side effects
c) Adverse event
d) None

(10) CDSCO stands for

a) Central Drugs Standard Control Organizati on
b) Central Drugs Safety Control Office
c) Central Drugs Safety Control Organization
d) Central Directory for Safety and Control of Organization

(11) Commonly reported ADR of diuretic class of drugs.

a) Alopecia
b) Hypokalemia
c) Skin cancer
d) Rhinitis

(12) That part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use

a) Gap analysis
b) Drug master file
c) Good manufacturing practices
d) Inter company transfer

(13) What is the purpose of the case report form?

a) To ensure data accuracy by providing a pla ce to store warehouse patient data for audit purposes
b) To provide a reference for all study subject s from which to analyze patient data
c) To include in the NDA filing
d) All of these

(14) What is the primary focus of Phase 3 Clinical testing?

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

(15) Full form of BLA is

a) Biologic license application
b) Biologic law application
c) Biologic license abbreviation
d) Biologic law abbreviation

(16) The _____ is the means through which the sponsor technically obtains thi s exemption from the FDA.

a) AND
b) AIND
c) INDA
d) IND

(17) The main components of ICSR is/ are

a) An identifiable patient
b) An adverse event
c) Susceptible drug
d) All of these

(18) In pharmacovigilance the term ADR stands for _____

a) Adverse Drug Reaction
b) Adverse Dose Reaction
c) Absolute Drug Reaction
d) Absolute Dose Reaction

(19) Animal studies, clinical trials, bioavailability studies are part of which application p rocess

a) NDA
b) IND
c) ANDA
d) BLA

(20) What is the importance of preclinical phase?

a) To determine pharmacokinetics and pharm acodynamics
b) Dose range and efficacy
c) Non human trial
d) None

(21) MedDRA is developed by

a) WHO
b) ICH
c) CDSCO
d) WHO-UMC

(22) _____ is an adverse event report for an individual patient and is source of d ata in pharmacovigilance

a) Drug reaction
b) ICSR
c) Teratogenicity
d) None

(23) PSUR stands for

a) Periodic safety update report
b) Public safety update report
c) Pacific survey on user report
d) None

(24) Mutual acceptance between

a) Europe
b) Japan
c) US
d) All of these

(25) IRB stands for

a) Ireland Recruitment Board
b) Institutional Review Board
c) International Research Board
d) International Reserve Bank

(26) CTD stands for

a) Computer tomographic design
b) Common technical document
c) Council of technical department
d) Common technical department

(27) The oldest quality control laboratory of the Drug Control Authorities in India is

a) Central Drugs Testing Laboratory, Kolkata
b) Central Drugs Testing Laboratory, Chenna i, Tamil Nadu
c) Central Drugs Testing Laboratory, Hyderab ad, AP
d) Central Drugs Testing Laboratory, Mumbai

(28) Periodic benefit risk evaluation report described in the _____

a) ICH-E2C
b) ICH-B2B
c) ICH-EC
d) None

(29) Inspection is a part of the _____

a) Quality planning
b) Quality circle
c) Quality improvement
d) Quality assurance and quality control

(30) Clinical studies come under

a) Quality guidelines
b) Safety guidelines
c) Efficacy guidelines
d) All of these

(31) Stability testing comes under

a) Quality guidelines
b) Safety guidelines
c) Efficacy guidelines
d) All of these

(32) Pharmacovigilance activities, especially in preparation for the early post marketing period of a new drug is known as _____planning.

a) A2C
b) E2E Pharmacovigilance
c) ABC
d) None

(33) _____ reactions, which are not directly related to drug dose (concentratio n) but can unusual patient phenotype.

a) Adverse drug
b) Carcinogenic
c) Idiosyncrasy
d) All of these

(34) Full form of ABC related to the drug transporter is_____.

a) ATP based casual transporter
b) ADP binding cassette transporter
c) ATP binding cassette transporter
d) None of these

(35) Drugs metabolizing enzymes are also called as

a) Metabolic biomarker
b) Reducer
c) Oxidizing agent
d) None of these

(36) The study of single genetic variations and their role in determining individual phar macokinetic and pharmacodynamics response to a drug is known as _____.

a) Pharmacodynamic
b) Pharmacokinetics
c) Pharmacogenomics
d) Pharmacogenetics

(37) The correct way(s) of data collection_____.

a) Spontaneous reports
b) Questionnaires
c) Elicited reports
d) All of these

(38) What is the full form of PDCO?

a) Pediatric committee
b) Paramedical and doctors cooperative
c) Pacific and developed countries organizati on
d) None of these

(39) Number of groups working in CIOMS.

a) 8
b) 4
c) 12
d) 13

(40) CDSCO is headed by

a) DCGI
b) DCC
c) Govt of India
d) Ministry of family and health welfare

(41) Rules 122A is permission for

a) To conduct clinical trial for investigational new drug
b) To import new drug
c) Definition of new drug
d) To manufacture new drug

(42) Rules 122DA is permission for

a) To conduct clinical trial for investigational new drug
b) To import new drug
c) Definition of new drug
d) To manufacture new drug

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

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

(44) What is the correct age group for pediatric patients?

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

(45) Schedule P is known as _____.

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

(46) Detailed information concerning a specific facility, process or product submitted to t he drug regulatory authority, intended for the incorporation into the application for marketing authorization known as

a) Gap analysis
b) Drug master file
c) Inter company transfer
d) Good manufacturing practices

(47) Full form of CFR is----------

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

(48) ICD stands for

a) Indian Classification of Disease
b) Inter Continental Diseases
c) Indian Council of Drugs
d) International Classification of Diseases

(49) As per ATC, drugs are classified into_____levels.

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

(50) INN stands for

a) International nonproprietary names for dru gs
b) International nonpotent names for drugs
c) Indian national names
d) None of these

(51) Drug regulatory agency of country Australia-----

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

(52) All medicines sold in South Africa must be registered by ……..

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

(53) Identify the relevant regulatory body in USFDA for approval of drugs.

a) BLA
b) IND
c) CBER
d) CDER

(54) In Europe, variations are classified as Type-IA for ….....change

a) Minor
b) Major
c) Moderate
d) Relative

(55) Which of the following is an International regulatory authority for drug regulation?

a) CDSCO
b) WHO
c) US-FDA
d) EMA

(56) In PCT, patent application enters national phase at_____months.

a) 12
b) 24
c) 30
d) 36

(57) The guideline ICH Q1A (R2) refers to

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

(58) Prior to 2004, EMA was known as

a) European Agency for the Evaluation of Medicinal Products
b) European Medicines External Agency
c) European Medicine Examination and Assessment
d) European Medicine Examination Agency

(59) If any organization wishes to market their product only in one EU country then_____ is preferred procedure.

a) National Procedures
b) Mutual recognition Procedure
c) Centralized Procedure
d) Decentralized Procedure

(60) _____ product does not require a BLA

a) Serum
b) Glucagon
c) Blood, blood component or derivative
d) Vaccine

(61) The headquarter of the WTO is located at _____

a) Geneva
b) Belgium
c) Austria
d) Czech

(62) _____programs aim to protect individuals against disease and also prevent the onward spread of disease within the population as a whole.

a) Immunization
b) Vaccination
c) ADR monitoring
d) Option a and b

(63) Based on antigen numbers, vaccine may be classified as

a) Monovalent
b) Polyvalent or multivalent
c) Both a and b
d) None

(64) Which one is not a type of live attenuated vaccine?

a) BCG
b) Hepatitis A
c) Oral polio vaccine
d) Rotavirus vaccine

(65) Types of vaccine_____

a) LAV
b) Toxoid
c) Subunit
d) All of these

(66) Which of the following AEFIs would be classified as a 'severe reaction'?

a) Vomiting, 5 minutes after receiving a BCG vaccination.
b) Fainting, 5 minutes after receiving a DTP vaccination.
c) Anaphylaxis, 5 minutes after receiving an Influenza-A vaccination.
d) Loss of appetite, 4 days after BCG vaccination.

(67) Which of the following onset intervals of severe adverse events following immunization is probably not due to the given vaccine?

a) Febrile seizures occurring 6–12 days following measles vaccination.
b) Anaphylaxis occuring 2–3 days after MMR vaccination.
c) Thrombocytopenia occurring 15–35 days after measles vaccine.
d) Vaccine-associated paralytic poliomyelitis (VAPP) occurring 4–30 days after OPV.

(68) Which option is/are methods of pharmacovigilance?

a) Overview of clinical trials
b) Post marketing surveillance
c) Laboratory access
d) All of these

(69) Which option is incorrect in regard to vaccine failure?

a) Age
b) Overweight
c) Infections
d) Immunity

(70) A _____study is constituted when data is collected from resident of patients durin g a specified interval of time or exposure of disease.

a) Case study
b) Study of patients
c) Cohort study
d) Cross survey study

(71) According to _____surveillance the reports describe AR, disease risk and heal th related events. It is a very common type of surveillance.

a) Active
b) Passive
c) Stimulated reporting
d) None

(72) _____communication is held between healthcare professionals and marketing a uthorization holders about the desired information.

a) Professional
b) Passive
c) Effective
d) Personal

(73) Who is responsible for WHO international drug monitoring Programme?

a) Uppsala Monitoring Center
b) FDA
c) EU
d) Japan

(74) Sentinel system was launched by FDA in -

a) 2008
b) 2001
c) 2010
d) 2009

(75) Indian Pharmacovigilance system is regulated by -

a) CDSCO
b) CFR
c) CDL
d) USFDA