

**4th YEAR, VIIITH SEMESTER EXAMINATION
2021-2022 (CARRYOVER)
BIOSTATISTICS AND RESEARCH METHODOLOGY**

[Max. Marks : 75]

- Explain in detail about T- test OR one way analysis of variance(ANOVA)
- Describe Wilcoxon rank test in detail.
- Explain in detail about various sources of data. How samples are collected for any research.

- Discuss the Importance of Biostatistic and Research methodology in Pharmaceutical Sciences.
- Explain mean, median and mode with example.
- Define Dispersion, range and standard deviation.
- Define Correlation coefficient (Karl Pearson's Coefficient).
- Define Probability and Binominal Distribution.
- Write the theory of Hypothesis. What is null Hypothesis?
- Explain error in sampling (Error type I and Error Type II).
- What is significant value? Write its importance.
- Application of regression analysis.

- i. A type-I error occurs when-
 - a) The null hypothesis is rejected when it is false
 - b) The null hypothesis is not rejected when it is false
 - c) The null hypothesis is not rejected when it is true
 - d) The null hypothesis is rejected when it is true

- ii. Which of the following is true about inter-quartile range?
- It describes the middle value of the distribution
 - It divides the distribution into two halves
 - It covers the middle 50% of observations
 - It is affected by the extreme values in the distribution
- iii. The Student's t test is:
- a parametric test
 - test a test for comparing medians
 - a nonparametric
 - a test for comparing variances
- iv. Which of the following is a non-probability sample ?
- Quota sample
 - Simple random sample
 - Purposive sample
 - (a) and (c) both
- v. When "n" is an odd number then median is defined as;
- Middle value
 - Median of two middle values
 - Sum of the values
 - Most repeated value
- vi. Parameters of standard normal distribution are;
- Mean
 - SD
 - Range
 - Both a and b
- vii. The area under normal distribution curve is-
- 1
 - 0.
 - 0
 - None of these
- viii. The square of the standard deviation is the:
- Variance
 - Mean
 - Standard error
 - Z-score
- ix. A statistical test which indicates the chance or probability of an observed difference between two means occurring by chance is called:
- Test of significance
 - Means
 - Ratio
 - Normalcy
- x. The variable which is influenced by the intervention of the researcher is called:
- Independent
 - Dependent
 - Discrete
 - Extraneous
- xi. In the scientific investigation, the first step is:
- Reporting your results
 - Perceiving a question.
 - Testing hypothesis.
 - Drawing conclusion.
- xii. Best graph for demonstration of relationship between ages and weight is:
- Bar diagram
 - Histogram
 - Scatter
 - Pie
- xiii. Shape of a normal curve is:
- Curvilinear
 - Linea
 - Symmetric
 - Parabolic
- xiv. Limits of confidence of a hypothesis is determined by:
- Power factor
 - Level of significance
 - 1- Power factor
 - 1- level of significance

- xv. In the Data View in the SPSS Data Editor, each row represents what?
- A case
 - A data point
 - A missing value
 - A variable
- xvi. In a factorial experiment ,the number of factors is the number of _____ variables.
- dependent
 - Independent
 - Extraneous
 - Compounding
- xvii. Who is the father of Biostatistics?
- John Snow
 - John Stuart
 - Francis Galton
 - None of the above
- xviii. The Arithmetic mean is the best measure of central tendency because:
- It is most stable measure
 - It is easy to calculate
 - It is based on all observations)
 - All of the above
- xix. Plagiarism can be defined as
- Representing another person's work/ words/ ideas--as your own.
 - Not acknowledging the sources your ideas build upon.
 - Paraphrasing another's ideas with explicit attribution to the author.
 - A & B
- xx. Who can successfully conduct Research?
- Someone who is a hard worker
 - Possesses post-graduation degree
 - Has studied research methodology
 - Possesses thinking and reasoning ability

Printing Pages :2

Paper Code : BP-802T C (SVSU:2021-22/R)

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B.PHARM
4th YEAR (VIII Semester) EXAMINATION
Social and Preventive Pharmacy (BP-802T)

[Time : 3:00 Hours]

[Max. Marks : 75]

MCQ: Answer All

[1x20=20]

1. DALY is:
 - a) Disease – Adjusted Life year
 - b) Disability Associated Life year
 - c) Disability Adjusted Life year
 - d) Disease Associated Life year
2. BCG vaccination is given:
 - a) Prodermally
 - b) Intradermally
 - c) Subcutaneously
 - d) Intramuscularly
3. Dengue shock syndrome is characterized by the following except:
 - a) Hepatomegaly
 - b) Thrombocytopenia
 - c) Pleural effusion
 - d) Decreased hemoglobin
4. Body mass index is also known as:
 - a) Quetelet's index
 - b) Broca's index
 - c) Lorentz's formula
 - d) None of The above
5. Highest protein content is in:
 - a) Red Gram
 - b) Soya Bean
 - c) Black Gram
 - d) Bengal Gram
6. Nuclear family consists of:
 - a) Husband, wife and son
 - b) Husband and wife only
 - c) Husband, wife and dependent children
 - d) Father mother husband and wife
7. Which of the following is an example of primary social relationship?
 - a) Husband and wife
 - b) Both
 - c) Author and publisher
 - d) None
8. Multi drug therapy (MDT) is treatment for:
 - a) TB
 - b) HIV
 - c) Leprosy
 - d) All of the above
9. Function of PHC are:
 - a) Referral services
 - b) Basic laboratory services
 - c) Family planning & referral services
 - d) All of the above
10. NRHM stand for?
 - a) National Register of Health Management
 - b) National Rural Health Mission
 - c) New Married Health Registration
 - d) None of the above
11. CHC stand for?
 - a) Centre for Hospital care
 - b) Chronic health Condition
 - c) Community health center
 - d) All of the above

12. Highest level of integration in health service is:
 - a) PHC c) CHC
 - b) Sub center d) District Hospital
13. Incubation period of COVID-19:
 - a) 7-14 Days c) 2 Days
 - b) 3 Months d) None of These
14. ASHA stand for:
 - a) A Social Health Agent c) Accredited Social Health Activist
 - b) A Specific Health Agent d) Advanced Scientific Health Activist
15. To prevent vertical transmission of HIV in a child of pregnant mother, used is:
 - a) Single dose of Nevirapine mother and child c) Zidovudine for 3 months
 - b) Observation d) Zidovudine for 6 months
16. 'DOTS' indicates:
 - a) Long-term treatment with supervision c) Short-term treatment without supervision
 - b) Long-term treatment without supervision d) Short-term treatment under supervision
17. Study of physical, social and cultural history of man is known as:
 - a) Social Science c) Sociology
 - b) Anthropology d) Life Science
18. Most powerful example of social cohesion is:
 - a) Hospital c) School
 - b) Family d) All of the above
19. Highest calcium concentration is present in:
 - a) Amla c) Guava
 - b) Dates d) Mango
20. Vitamin E rich Foods are:
 - a) Sun Flower Oil c) Wheat germ oil
 - b) Soya oil d) Advanced Scientific Health Activist

Short Answer: Answer any Seven

[5x7=35]

1. Discuss role of PHC (Primary Health Center) in social health.
2. Give a short note on definitions and concept of health.
3. Write a note on Balanced diet and Nutritional deficiencies
4. Write a note on personal hygiene and health care; avoidable habits.
5. Briefly explain relatedness of Poverty and health.
6. Discuss Socio cultural factors related to health and disease.
7. Discuss vitamin deficiencies illness its prevention.
8. Discuss principles of prevention and control of SARS-COVID.

Long Answer: Answer any two

[10x2=20]

1. Write about drug addiction, drug substance abuse and its prevention.
2. Write prevention and control of ANY TWO diseases- pneumonia, hypertension, and diabetes mellitus.
3. Write objectives, functioning and outcome of ANY TWO-
 - a) HIV AND AIDS control programme,
 - b) Universal immunization programme
 - c) Pulse polio programme

Printing Pages : 2

Paper Code : BP804ET C (SVSU:2021-22/C)

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B.Pharm

IVth Year, VIIIth Semester 2021-22 (Carry Over)

Pharmaceutical Regulatory Science

[Time -3 hr.]

[MM-75 marks]

Attempt all questions. Each question carries equal marks.

Q.1. Answer *ALL* of the following: (1×20 = 20)

1. How many drugs can be imported under single Form 11 license?

- a) 20 b) 5 c) 10 d) 15

2. List of approved drugs and their associated IPR is available in ____.

3. Identify the relevant regulatory body in USFDA for approval of drugs.

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

4. In US the Orphan Drug Exclusivity (ODE) last foryears.

5. As per ANDA requirements the bioequivalence of test to reference formulation is

- a) 80-120% b) 100-150% c) 70-80% d) 20-50%

6) Average time period for phase II clinical trials study is ____.

- a) UPTO 4 yrs b) UPTO few months c) UPTO two years
d) UPTO several years

7) Suggest how many people will be selected for phase II trial

- a) The whole market will be under surveillance
b) 300-3000 people c) 20-300 people d) 50 people

8) Full form of CDSCO _____.

9) Full form of IRB is Institutional Review Board. (True/False).

10) Who is Australia's regulatory body?

- a) TGA b) GTA c) TAG d) ALL

11. Which of the following is an International regulatory authority for drug regulation?

- a) CDSCO b) USFDA c) WHO d) EMA

12. Indian Pharmacopoeia Commission headquarter is located at

- a) Delhi b) Ghaziabad c) Chennai d) Mumbai

13. The 1st edition of Indian Pharmacopoeia was published in the year
a)1955 b)1950 c)1945 d)1965
14. In PCT, patent application enters national phase at.
a)12 Month b)24 Month c)30 Month d)36 Month
15. Copyrights is granted for_
a) Pharmaceutical product b)Logo
c) Music and Literature d)None
16. The term of patent is valid for the period of 20 years from the
a)Date of Approval b)Date of Exam
c)Date of Publication d)Date of Filling of application
17. The WHO international drug monitoring programme was established in the year.
a)1968 b)1983 c)1974 d)1962
18. Serious adverse event.
a) Result in death b) Cover within 1 month
c) Result in defects of body d) Mental Illness
19. EMR is _____.
20. _____ is an example of Category X drugs.
a) Diclofenac b)Paracetamol c)Lorazepam d)All of these

Q.2 Attempt any two:

(2×10 = 20)

1. Write about organizational structure and types of application of regulatory authorities and agencies.
2. Write about Independent ethics committee, its formation and working procedure.
3. Discuss organization, structure and types of applications of regulatory authorities of India.

Q.3 Attempt any Seven:

(7×5 = 35)

1. Explain Pharmacovigilance safety monitoring in clinical trials.
2. Discuss ASEAN in detail.
3. Write the concept of orange book.
4. Discuss stages of drug discovery.
5. Write about drug development process.
6. Explain GLP in detail.
7. Write a short note on GMP.
8. Discuss concepts of generic drug and product development.
9. Write a note on new drug application (NDA)

Printing Pages :2

Paper Code : BP-805ET B (SVSU:2021-22/R)

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B.PHARM
4th YEAR (VIII Sem.) CARRYOVER EXAMINATION
Pharmacovigilance (BP-805ET)

[Max. Marks : 75]

[Time : 3:00 Hours]

[1x20=20]

MCQ: Answer All

- What are the 4 topics covered by ICH?
 - Quality, safety, evaluation and licensing
 - Safety, efficacy, licensing and quality
 - Quality, safety, evaluation and multidisciplinary
 - Quality, safety, efficacy and multidisciplinary
- What does FDA stand for?
 - Federal Drug Association
 - Federal Drug Administration
 - Food & Drug Association
 - Food & Drug Administration
- What does the I stand for in IRB?
 - Investigational
 - International
 - Institutional
 - Internal
- Randomization technique is/are:
 - Block
 - Simple
 - Stratified
 - All of the above
- What is the term used to describe the process of providing information about a clinical trial to a child and asking if they would like to take part?
 - Consent
 - Proxy consent
 - Assent
 - Assertion
- Which ICH Guideline provides definitions and standards for expedited reporting of adverse events?
 - E2A
 - E2C
 - E2B
 - E2D
- According to ICH all noxious and unintended responses to a medicinal product related to any dose should be considered what?
 - Adverse Events
 - Side Effect
 - Adverse Drug Reactions
 - Serious Adverse Events
- Pharmacovigilance means:
 - Monitoring of drug safety
 - Monitoring pharma students
 - Monitoring of unethical trade of drugs
 - Monitoring pharma students
- Good clinical practice (GCP) is not required in:
 - Phase I trial
 - Phase II studies
 - Preclinical Phase
 - Phase IV studies
- Stage IV clinical trial is also called as:
 - Human pharmacology and safety
 - Therapeutic exploration and dose ranging
 - Postmarketing surveillance
 - None of the above

11. Placebo is:
 - a) The subjects do not know which study treatment they receive
 - b) Drug with therapeutic benefit
 - c) Fake treatment
 - d) All of the above
12. NDA is:
 - a) New Drug Application
 - b) Investigation Application
 - c) Investigation of New Drug Application
 - d) No Drug Application
13. What ethical principles are cited in the principles of ICH GCP?
 - a) Declaration of Helsinki
 - b) Applicable regulatory requirements
 - c) GCP
 - d) All of these
14. What does MedRA stand for:
 - a) Medical Regulatory Agency
 - b) Medical Devices Regulations Authority
 - c) Medical Dictionary for Regulatory Activities
 - d) Medical Dictionary for Routine Assessments
15. What is GCP?
 - a) Good cooperation project
 - b) Good cleanliness practice
 - c) Good clinical practice
 - d) Good Constructor provider
16. In which phase pharmacodynamics and pharmacokinetics of a drug are studied?
 - a) Phase I
 - b) Phase II
 - c) Phase III
 - d) Phase IV
17. Which of the following refers to a dosing description that means that treatment should be taken as needed?
 - a) PRN
 - b) TDS
 - c) OD
 - d) BD
18. What is meant by blind subject?
 - a) The subjects do not know which study treatment they receive
 - b) Patients injected with placebo and active doses
 - c) Fake treatment
 - d) Signed document of the recruited patient for the clinical trial procedures
19. LD50/ED50 is a measure for:
 - a) Affinity
 - b) Therapeutic index
 - c) Potency
 - d) Toxicity
20. What is informed consent in a clinical trial?
 - a) The subjects do not know which study treatment they receive
 - b) Patients injected with placebo and active doses
 - c) Fake treatment
 - d) Signed document of the recruited patient for the clinical trial procedures

Short Answer: Answer any Seven

[7X5=35]

1. Write Definitions and classification of ADRs.
2. Discuss various Pharmacovigilance methods.
3. Briefly explain MedDRA and Standardised MedDRA queries.
4. Write a note on Pharmacovigilance Program of India (PvPI).
5. Write a short Note on Spontaneous reports and Stimulated reporting.
6. Write in details about Expedited reporting.
7. Write about CIOMS.
8. What is Clinical trial? Discuss phases of clinical trials.

Long Answer: Answer any two

[2X10=20]

1. Discuss Pharmacovigilance guidelines and Reporting of ADR in India.
2. Write in details note on ICH Guidelines for Pharmacovigilance.
3. Write History and development of Pharmacovigilance.