

B.PHARM**IVYEAR, VIIIth SEMESTER EXAMINATION****Biostatistics and Research Methodology (CODE-BP 801T)****[Time: 3:00 Hrs.]****[Max. Marks: 75]****Q1. Long Question: Answer Any two****[10×2=20]**

- a) Compute the mode of the following distribution-
- | | | | | | | | |
|------------|-------|-------|-------|-------|-------|-------|-------|
| Class: | 10-20 | 20-30 | 30-40 | 40-50 | 50-60 | 60-70 | 70-80 |
| Frequency: | 22 | 35 | 40 | 62 | 50 | 45 | 40 |
- b) From the following data find the regression line Y on X -
- | | | | | | |
|-------|---|---|---|---|---|
| x : | 1 | 2 | 3 | 4 | 5 |
| y : | 2 | 5 | 3 | 8 | 7 |
- c) Define sample. Discuss various methods of sampling.

Q2. Short Question: Answer any Seven**[5×7=35]**

- a) Define biostatistics. Give the applications and limitations of statistics in biological sciences.
- b) Discuss various steps involved in testing of hypothesis.
- c) Define correlation and discuss the types of correlation.
- d) What are the various methods used for representing a frequency distribution graphically?
- e) Write a note on sampling errors.
- f) Give merits and demerits of median.
- g) What do you mean by dispersion? What are the methods of computing dispersion.
- h) Write in brief about need of research.
- i) From the data given below calculate interquartile range, quartile deviation and its coefficient-
87, 36, 95, 99, 55, 62, 48, 71, 50, 65, 90

Q3. Multiple choice questions. (Answer all)**[1×20=20]**

- i. A Type II error occurs when-
- a null hypothesis is rejected but should not be rejected
 - a null hypothesis is not rejected but should be rejected
 - a test statistic is incorrect
 - None of the above
- ii. The student's t test is:
- a parametric test
 - a nonparametric test
 - a test for comparing variances
 - None of the above
- iii. When mean, median, and mode lie in the centre of the curve, the distribution is known as-
- Right skewed
 - left skewed
 - Normal
 - None of the above

- iv. In 95 percent confidence interval, the level of significance is-
 a. 0.01 b. 0.05 c. 0.1 d. None of the above
- v. Shape of a normal curve is-
 a. Symmetrical b. Curvilinear b. Linear d. Parabolic
- vi. Statistical regression includes-
 a. Forward selection b. Backward deletion
 c. Step wise regression d. All of the above
- vii. Binomial probability distribution is a-
 a. Discrete distribution b. Continuous distribution
 c. Semi-continuous distribution d. None of the above
- viii. The parameter of the Poisson distribution is m which is-
 a. Mean of the distribution b. Standard deviation of the distribution
 c. Both d. None of these
- ix. Correlation coefficient was given by-
 a. Karl Pearson b. Fisher c. Spearman d. None of the above
- x. Normal distribution is a-
 a. Discrete distribution b. Continuous distribution
 c. Semi-continuous distribution d. None of the above
- xi. Who is the father of Biostatistics?
 a. Francis Galton b. John Snow c. John Stuart d. None of the above
- xii. The term biometry was coined by:
 a. Fischer b. Francis Galton c. Karl Pearson d. Walter Weldon
- xiii. The word "Statistik" in German means:
 a. Calculation b. Government c. Maths d. Classification
- xiv. The Arithmetic mean is the best measure of central tendency because:
 a. It is most stable measure b. It is easy to calculate
 c. It is based on all observations d. All of the above
- xv. Standard deviation is always measured from-
 a. Median b. Mean c. Mode d. Zero
- xvi. Easiest method of measuring the dispersion is-
 a. Mean deviation b. Standard deviation
 c. Range d. Quartile deviation
- xvii. What is the mode in statistics?
 a. Value of middle observation b. Arithmetic mean
 c. Most commonly occurring value
 d. Difference between the highest and lowest value
- xviii. First step in calculating median is-
 a. Calculate range b. Arrange data c. Count the data d. None of these
- xix. All the following are measures of dispersion except-
 a. Mean b. Variance c. Standard deviation d. Range
- xx. Find the mode of the call received on 7 consecutive days
 11, 13, 13, 17, 19, 23, 25-
 a. 11 b. 13 c. 17 d. 23

Printing Pages: 2

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

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B.PHARM

4th YEAR (VIII Sem.) EXAMINATION
Social and Preventive Pharmacy (BP802T)

[Time : 3:00 Hours]**[Max. Marks : 75]****I. Multiple Choice Questions (MCQ)****[1x20=20]**

1. CHC stand for?
 - a) Centre for Hospital care
 - b) Chronic health Condition
 - c) Community health center
 - d) All of the above
2. To prevent vertical transmission of HIV in a child of pregnant mother, used is:
 - a) Single dose of Nevirapine to mother and child
 - b) Observation
 - c) Zidovudine for 3 months
 - d) Zidovudine for 6 months
3. Study of physical, social and cultural history of man is known as:
 - a) Anthropology
 - b) Social Science
 - c) Life Science
 - d) Sociology
4. Most powerful example of social cohesion is:
 - a) School
 - b) Family
 - c) Hospital
 - d) All of the above
5. Full form of SARS is:
 - a) Severe Acute Respiratory syndrome
 - b) Severe Access Respiratory syndrome
 - c) Severe Acute Record syndrome
 - d) None of These
6. NRHM stand for?
 - a) National Register of Health Management
 - b) National Rural Health Mission
 - c) New Married Health Registration
 - d) None of the above
7. ASHA stand for:
 - a) A Social Health Agent
 - b) A Specific Health Agent
 - c) Accredited Social Health Activist
 - d) Advanced Scientific Health Activist
8. Highest level of integration in health service is:
 - a) PHC
 - b) Sub center
 - c) CHC
 - d) District Hospital
9. Incubation period of COVID-19:
 - a) 7-14 Days
 - b) 3 Months
 - c) 2 Days
 - d) None of These
10. 'DOTS' indicates:
 - a) Long-term treatment with supervision
 - b) Long-term treatment without supervision
 - c) Short-term treatment without supervision
 - d) Short-term treatment under supervision
11. Vitamin E rich Foods are:
 - a) Sun Flower Oil
 - b) Soya oil
 - c) Wheat germ oil
 - d) Advanced Scientific Health Activist
12. DALY is:
 - a) Disease – Adjusted Life year
 - b) Disability Associated Life year
 - c) Disability Adjusted Life year
 - d) Disease Associated Life year
13. BCG vaccination is given:
 - a) Prodermally
 - b) Intradermally
 - c) Subcutaneously
 - d) Intramuscularly

14. Body mass index is also known as:
 - a) Quetelet's index
 - b) Broca's index
 - c) Lorentz's formula
 - d) None of The above
15. Highest protein content is in:
 - a) Red Gram
 - b) Soya Bean
 - c) Black Gram
 - d) Bengal Gram
16. 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
17. Which of the following is an example of primary social relationship?
 - a) Husband and wife
 - b) Both
 - c) Author and publisher
 - d) None
18. Multi drug therapy (MDT) is treatment for:
 - a) Leprosy
 - b) HIV
 - c) TB
 - d) All of the above
19. Function of PHC are:
 - a) Referral services
 - b) Basic laboratory services
 - c) Family planning & referral services
 - d) All of the above
20. Dengue shock syndrome is characterized by the following except:
 - a) Hepatomegaly
 - b) Thrombocytopenia
 - c) Pleural effusion
 - d) Decreased hemoglobin

II. Short Answer: Answer any Seven

[5x7=35]

1. Discuss Concept of health in detail.
2. Write short notes on Balanced diet and Nutritional deficiencies
3. Discuss effect of personal hygiene on health.
4. Discuss Socio cultural factors related to health and disease.
5. Write about National health mission (NRHM and NUHM).
6. Write the importance of social and health education.
7. Write note on pulse polio programme.
8. Discuss principles of prevention and control of SARS-COVID-19.
9. Write note on sociology and health.

III. Long Answers (Answer 2 out of 3)

[10x2=20]

1. Write prevention and control of ANY TWO diseases- hypertension, diabetes mellitus, and cancer.
2. Write in details about HIV AND AIDS control programme.
3. Discuss role of PHC (Primary Health Center) in rural, urban and school health

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Paper Code : BP-803ET B (SVSU:2021-22/R)

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B.PHARM**4th Year 8th SEM. Examination****Pharmaceutical Marketing Management (BP-803ET)****[Time: 3:00 Hours]****[Max. Marks: 75]****Q1. Attempt ALL questions.****(1X20=20)**

- a) Marketers often use the term to cover various groupings of customers.
 (i) Demographic segment (ii) People
 (iii) Buying power (iv) Market
- b) The buying process starts when the buyer recognizes a
 (i) An advertisement for the product
 (ii) A salesperson from a previous visit
 (iii) Problem or need
 (iv) Product
- c) Parents buy toys for their children act asin the buying process.
 (i) Decider (ii) Buyer (iii) Maintainer (iv) All of these
- d) markets are made up of members of the distribution chain.
 (i) Business to business (ii) Channel
 (iii) Consumer (iv) Institutional
- e) Which of the following is considered a "key player" in the marketing industry?
 (i) Suppliers or vendors (ii) Marketer
 (iii) Distributors or retailer (iv) All of these
- f) Market where goods are transacted on the spot or immediately
 (i) Future market (ii) Perfect market
 (iii) Spot market (iv) None of these
- g) Market which are organized and regulated by statutory measure are
 (i) Regulated market (ii) Unregulated market
 (iii) World market (iv) None of these
- h) The markets in which goods are bought and sold in bulk quantities
 (i) Retail market (ii) World market
 (iii) Wholesale market (iv) None of these
- i) Market in which gold and silver are sold
 (i) Commodity market (ii) Produce market
 (iii) Bullion market (iv) None of these
- j) Market where money is lend and borrowed
 (i) Money Market (ii) Foreign exchange market
 (iii) Stock market (iv) None of these
- k) Which of the following is not included in the micro environment
 (i) Suppliers (ii) Economic (iii) Customers (iv) Public
- l) "We guarantee every product we sell" appeal to motive.
 (i) Curosimy (ii) Variety (iii) Quality (iv) Comfort

[1]

- m) The negative feeling which arises after purchase causing inner tension is known as
- (i) Cognitive dissonance
 - (ii) Post purchase dissonance
 - (iii) Buyer's remorse
 - (iv) All of these
- n) The essential criteria for effective segmentation is
- (i) Homogeneity
 - (ii) Measurability
 - (iii) Profitability
 - (iv) All of these
- o) Which of the following is included in the new product development strategies
- (i) Idea generation
 - (ii) Idea screening
 - (iii) Product development
 - (iv) All of these
- p) Marketing is applicable in
- (i) Goods
 - (ii) Events
 - (iii) Property
 - (iv) All of these
- q) Market where there is no physical delivery of goods
- (i) Spot market
 - (ii) Perfect market
 - (iii) Future market
 - (iv) None of these
- r) Risk bearing is a function of
- (i) Research
 - (ii) Facilitating
 - (iii) Exchange
 - (iv) Physical supply.
- s) Market is important to
- (i) Economy
 - (ii) Companies
 - (iii) Consumers
 - (iv) All of these
- t) Profit through customer satisfaction is aimed in Concept.
- (i) Marketing
 - (ii) Holistic
 - (iii) Production
 - (iv) Selling

Q2. Answer any TWO questions. (10X2=20)

- a) Give an overview of National Pharmaceutical Pricing Authority.
- b) Explain the various steps of new product development strategies with suitable example.
- c) Describe the different methods of sale promotions technique with suitable example.

Q3. Answer any SEVEN questions. (5X7=35)

- a) Define marketing environment and explain in a brief about macro & micro environment.
- b) Give an account of pharmaceutical channels.
- c) Differentiate between generic and branded product.
- d) What are the qualities and duties of professional sales representative?
- e) Define marketing? Describe the various functions and scope of marketing.
- f) Discuss planning as a function of management.
- g) Write a note on advertising and publicity as elements of promotion.
- h) What are the effects of different elements of marketing mix on different stages of PLC?
- i) Discuss on personnel selling pharmaceutical products? Add a note on advantages and disadvantage of personal selling.

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FOURTH YEAR, EIGHTH SEMESTER EXAMINATION
Pharmaceutical Regulatory Science (BP804ET)

TOTAL MARKS: 75

2) All questions carry equal marks.

(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. Which of the following is an International regulatory authority for drug regulation.
a) CDSCO b) USFDA c) WHO d) EMA
7. Indian Pharmacopoeia Commission headquarter is located at
a) Delhi b) Ghaziabad c) Chennai d) Mumbai
8. The 1st edition of Indian Pharmacopoeia was published in the year
a) 1955 b) 1950 c) 1945 d) 1965
9. In PCT, patent application enters national phase at.
a) 12 Month b) 24 Month c) 30 Month d) 36 Month
10. Copyrights is granted for_____
a) Pharmaceutical product b) Logo c) Music and Literature d) None
11. The guidelines for good manufacturing practice in India is.
a) 21 CFR Part 4 b) 21 CFR Part 211 c) Schedule M d) None
12. Drug regulatory body of Brazil is_____
a) TGA b) SFDA c) ANVISA d) MHLWD
13. ASMF stands for_____.
14. Are those drugs that are available to consumers without a prescription
a) Old Drug Products b) New drug Products c) OTC drug d) All of these
15. The means through which the sponsor technically obtains this exemption from the FDA
a) AND b) INDA c) ANDA d) INDIA
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 Filing of application
17. The WHO international drug monitoring programme was established in the year.
a) 1968 b) 1983 c) 1974 d) 1962
18. The pharmacovigilance programme of india (pvpi) coordinated by the surveillance of pharmacovigilance.
a) Calcutta b) Ghaziabad c) Delhi d) Tamilnadu
19. Regulatory body of Singapore-
a) Health Science Authority (HAS) b) HPPS c) Thai PBS d) Health ministry Singapore
20. Adverse event is due to
a) Life threatening b) Due to drug/treatment c) Both d) None

(2×10 = 20)

1. Write about organizational structure and types of application of regulatory authorities and agencies.
2. Explain regulatory approval process (ANDA).
3. Discuss ICH in detail

(7×5 = 35)

1. Discuss stages of drug discovery.
2. Write about drug development process.
3. Write about approval process and timelines involved in NDA Approval.
4. Discuss in brief about overview of regulatory authorities of India.
5. Write a brief note on Common technical documents.
6. Discuss about IB (Investigational Brochure).
7. Discuss developing clinical trial protocols.
8. Explain pharmacovigilance safety monitoring in clinical trials.
9. Explain the concept of IP Monographs.

Printing Pages : 2

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

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B.Pharm

4th Year 8th SEM. EXAMINATION

Pharmacovigilance, (BP 805 ET)

[Time : 3:00 Hours]

[Max. Marks : 75]

I. Multiple Choice Questions (MCQ)

[20×1=20]

1. Pharmacovigilance is used:

- (a) to monitor drug toxicity
(b) to monitor unauthorized drug manufacture
(c) to monitor Efficacy of the drug
(d) none of these

2. What is GCP?

- (a) Good cooperation project
(b) Good clinical practice
(c) Good cleanliness practice
(d) All of These

3. Type A ADRS are :

- (a) Predictable (b) Idiosyncratic (c) Chronic effects (d) Delayed effects

4. Methods in causality assessment involves

- (a) Expert judgment/global introspection
(b) Algorithms
(c) Probabilistic methods
(d) all of these

5. 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) None of These

6. What is the main Purpose of ATC& DDD?

6. What is the main purpose of Drug Utilization (DU) research?
- “International language for Drug Utilization (DU) research”
 - Tool for presenting DU research
 - Improves quality of drug use Presentation & comparison of drug consumption statistics at national & international level.
 - all of these

7: Stage IV of clinical trial is also called....

- (a) Human pharmacology and safety (b) Post marketing surveillance
(c) Therapeutic exploration and dose ranging (d) Therapeutic confirmation

8. J Seigel and PJ Schneider categorized ADRs into levels of severity.

- (a) seven (b) Five (c) three (d) Two

9. What is placebo

9. What is placebo
- (a) Fake treatment (b) the subjects do not know which study treatment they receive
(c) Patients injected with placebo and active doses (d) None of These

10. Who can report adverse drug reaction?

10. Who can report adverse drug reaction:
(a) Doctors (b) Dentists (c) Pharmacists (d) all of these

11. What does AEFI stands for

11. What does AEFI stands for
- (a) Adverse Events Following Immunization (b) Adverse Events Following Immunity
- (c) Both a and b (d) None of These

12. what does CRO stands for in Pharmacovigilance

12. what does CRO stand for in Pharmacovigilance
(a) Contract Research Organization (b) Clinical Research Organization
(c) Both a and b (d) None of These

13. which is the example of Tertiary Resources in Pharmacovigilance

- (a) textbooks (b) Abstract (c) Journal articles (d) none of these

14. What does MedRA stand for?
 (a) Medical Regulatory Agency (b) Medical Dictionary for Regulatory Activities
 (c) Medical Devices Regulations Authority (d) None of These
 15. What does ANOVA stand for?
 (a) Analysis of Visual Analogues (b) Analysis of Virtual Analogues
 (c) Analysis of Variance (d) Analysis of Variability.
 16. What does the A stand for in ADME?
 (a) Absorption (b) Antibiotic (c) Auto (d) All of These
 17. What does FDA stand for?
 (a) Federal Drug Association (b) Food & Drug Association
 (c) Federal Drug Administration (d) Food & Drug Administration
 18. What does SUSAR stand for?
 (a) Serious unrelated suspected adverse reaction
 (b) Suspected unexpected serious adverse reaction
 (c) Suspected untoward serious adverse reaction (d) None of These
 19. Which ICH Guideline provides definitions and standards for expedited reporting of adverse events?
 (a) E2A (b) E2B (c) E2C (d) E2D
 20. What do I stand for in IRB?
 (a) Investigational (b) Institutional (c) International (d) Internal
- II. Long Answers (Answer 2 out of 3) [2×10=20]**

1. Define Pharmacovigilance and write about Pharmacovigilance Program of India?
2. Classify Adverse Drug reactions and write in detail about detection and reporting of adverse drug reaction?
3. Write in Detail about ICH Guidelines for Pharmacovigilance?

III. Short Answers (Answer 7 out of 9) [7×5=35]

1. Write methods involve in Severity and seriousness assessment?
2. Write Note on Pharmacogenomics?
3. Write short note on CIOMS?
4. Discuss the information resources in Pharmacovigilance?
5. What do you mean by MEDRA write the application of MEDRA in Pharmacovigilance?
6. Write short notes on Anatomical, therapeutic and chemical classification of drugs?
7. Write note on Drug safety evaluation in special population?
8. Explain vaccine safety surveillance in detail?
9. Write note on CDSCO?

Experimental Pharmacology, BP.810 ET

[Max. Marks : 75]

[20×1=20]

- [17]

16. Commonly used laboratory animal.....
 (I) rat (II) rabbit (III) guinea pig (IV) all of these
17. Sacrificing The Experimental Animal After Use By Gentle Procedure Causing Minimum Of Physical And Mental Suffering Is
 (I) Euthanasia (II) analgesia (III) Anesthesia (IV) none of these
18.is the example of Inhalant agents
 (I) ether (II) halothane (III) isoflurane (IV) all of these
19. IP route means
 (I) Intra-pores (II) Intra-potassium (III) Intra-parenteral (IV) Intra-peritoneal
20. SC injection means ...
 (I) Subcutaneous (II) Sub-cranium (III) Sub-chronic (IV) none of these
- II. Long Answers (Answer 2 out of 3) [2×10=20]**

1. Write in detail about CPCSEA guidelines for maintenance, breeding and conduct of experiments on laboratory animals?
 2. Write any two pre clinical screening model for anti inflammatory and anti-depressant?
 3. Discuss in detail about routes of drug administration in laboratory animals?
- III. Short Answers (Answer 7 out of 9) [7×5=35]**

1. Write pre clinical screening model for Analgesics.
2. Discuss pre clinical screening model for anti ulcer drug.
3. Write any two pre clinical screening model for Sympathomimetics.
4. Write short notes on transgenic animals.
5. Write notes on Techniques for collection of blood in animals.
6. Write any two preclinical screening models for anti diabetics.
7. Write pre clinical screening model for sedative and hypnotics.
8. Write pre clinical screening model for antipyretic drugs..
9. Write pre clinical screening model for diuretics.