

**Bachelor of Pharmacy**  
**Eighth Semester Main Examination, June-2021**  
**Biostatistics and Research Methodology [BP-801T]**

**Time: 3:00 Hrs****Max Marks 75**

- Note :** (i) All parts of the question paper are compulsory.  
(ii) All question of each part to be attempt at one place.

**Part-A****Q.1 Multiple Choice Questions.****[1×20 = 20 Marks]**

- (i) The application of statistical method in biology is called-  
(a) Statics in biology (b) Statics in Vivo  
(c) Biostatistics (d) All of this
- (ii) Who is regarded as father of as Biostatistics-  
(a) Fisher (b) Karl Pearson  
(c) Francis Galton (d) Francis bacon
- (iii) The term biometric was coined by -  
(a) Fischer Karl Pearson (b) Water Beldon  
(c) Both a and b (d) Francis Galton
- (iv) The branch of biostatic that deal with method of collection organization and presentation of data is called as -  
(a) Inferential biostatistics (b) Descriptive biostatistics  
(c) Both a n d comparative (d) Biostatistics
- (v) In biostatistics group of individuals taken for study is called-  
(a) Block (b) Population  
(c) Group (d) Flock
- (vi) The word statics in German means-  
(a) Calculations (b) Government  
(c) Mathematics (d) Classification
- (vii) Biostatistics is also called as-  
(a) Statistics in biology (b) Bionemorology  
(c) Biometry (d) Both A and B
- (viii) The characteristics or quantity that may vary from one individual to another is called-  
(a) Static group (b) Variables  
(c) Dynamic group (d) Dynamism
- (ix) Variable whose value can be expressed numerically are called-  
(a) Quantitative variables (b) Qualitative variables  
(c) Absolute variables (d) Continuous variables
- (x) Chi square test-  
(a) Measure the degree of deviation experimental results from the expected results  
(b) To test the closeness of observed and expected results  
(c) To test the population variances and test variances

- (d) All the above
- (xi) Find the mode of the following 11, 12, 13, 14-  
 (a) 11 (b) 12  
 (c) 13 (d) 1
- (xii) Which of the following is not measure of Central tendency-  
 (a) Mean (b) Mode  
 (c) Median (d) Range
- (xiii) Standard deviation is the square of-  
 (a) Mean mode (b) Standard error  
 (c) Variance (d) Regression
- (xiv) Correlation coefficient is a number between-  
 (a) 1 and 2 (b) 0 and 1  
 (c) 1 and 0 (d) -1 and +1
- (xv) CHI square is zero when-  
 (a) Expected frequency is lesser than observed frequency  
 (b) Expected frequency is equal to observed frequency  
 (c) Expected frequency is double of the observed frequency  
 (d) Expected frequency is greater than the observed frequency
- (xvi) A circle divided into sectors proportional to the frequency of item shown is called-  
 (a) Bar chart (b) Pie chart  
 (c) Histogram (d) Frequency polygon
- (xvii) A statistical test can be utilized to validate the statement peoples having high cholesterol suffer more from hypertension-  
 (a) A student test (b) Deregulation analysis  
 (c) Pearson correlation coefficient (d) Annova
- (xviii) To determine variation in wings length of butterfly from five different places would be best statically test CSIR 2009-  
 (a) F test (b) Student test  
 (c) Regression analysis (d) Chi square test
- (xix) Height of student in a class is a-  
 (a) Quantitative variables (b) Discrete variables  
 (c) Absolute variables (d) Continuous variables
- (xx) Number of fruits in a tree is a-  
 (a) Quantitative variables (b) Discrete variables  
 (c) Absolute variables (d) Continuous variables

### Part-B

- Q.2 Short answer type questions. (Any seven) [5×7 = 35 Marks]**
- (a) What do you mean by multiple regressions, standard error of regression pharmaceutical examples probability?
- (b) Explain in detail of Probability, Binomial Distribution.
- (c) Define central composite design.
- (d) What do you mean by historical design?
- (e) Explain curve fitting method of least square.
- (f) Explain in detail the definition of probability binomial distribution.
- (g) Give in detail sampling error and large sample is small sample.

- (h) Explain in detail Students-t test and ANOVAs test.
- (i) What do you mean by designing and sample size determination.

**Part-C**

**Q.3 Long answers type questions. (Any two) [10×2 = 20 Marks]**

- (a) What do you mean by industrial and clinical trial approach and which software use in industry.
- (b) Explain in detail factorial design and advantages of factorial design.
- (c) Explain in detail of normal distribution, Poisson's distribution.

Enrollment No.....

**Bachelor of Pharmacy  
Eighth Semester Main Examination, June-2021  
Social and Preventive Pharmacy [BP802T]**

**Time: 3:00 Hrs**

**Max Marks 75**

- Note :** (i) All parts of the question paper are compulsory.  
(ii) All question of each part to be attempt at one place.

**Part-A**

**Q.1 Multiple choice questions- [1x20 = 20 Marks]**

- (i) Non Profit NGO in India situated is -
  - (a) ARMMAN
  - (b) Nagpur
  - (c) Both A and B
  - (d) None of the above
  
- (ii) Symptoms of acute Respiratory Infections -
  - (a) Common cold
  - (b) Sinusitis
  - (c) Ear infections
  - (d) All of the above
  
- (iii) ..... benefit of good hygiene is having better health -
  - (a) Wealth
  - (b) Personnel hygiene
  - (c) Public health
  - (d) None of these
  
- (iv) Symptoms of cholera disease -
  - (a) Diarrhea -
  - (b) Nausea and vomiting
  - (c) Dehydration
  - (d) All of the above
  
- (v) National health intervention programme for mother and child mission -
  - (a) To protect for elder
  - (b) To protect for young
  - (c) None of the above
  - (d) To protect for mother and child
  
- (vi) How many Type of vitamins -
  - (a) 10
  - (b) 13
  - (c) 11
  - (d) 5

- (vii) Common symptoms of Cancer -
- (a) Lumps
  - (b) Pimples
  - (c) Malignant tumor
  - (d) None of the above
- (viii) .....is a lung infection that is usually *caused by* a virus or bacteria.
- (a) Diabetic
  - (b) Pneumonia
  - (c) Cholera
  - (d) Cancer
- (ix) Example of improvement in rural sanitation -
- (a) Rooms
  - (b) Services
  - (c) Toilets facilities
  - (d) None of the above
- (x) Drug used in treatment of Tuberculosis -
- (a) Isoniazid
  - (b) Rifampicin
  - (c) Pyrazinamide
  - (d) All of the above
- (xi) Social problem means -
- (a) State of affairs
  - (b) Moral approach to problem
  - (c) Personal problem
  - (d) Family problem
  - (e) None of the above
- (xii)..... is an infectious disease that causes severe watery diarrhea -
- (a) Cholera
  - (b) Malaria
  - (c) Cancer
  - (d) None of the above
- (xiii) Universal immunization programme mission
- (a) To protect immune system
  - (b) To protect new born baby
  - (c) Young & children
  - (d) None of the above
- (xiv) The headquarters of W.H.O
- (a) Geneva, Switzerland
  - (b) Japan
  - (c) South Africa
  - (d) West Indies
- (xv) .....is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.
- (a) Wealth
  - (b) Health
  - (c) Money
  - (d) Waste
- (xvi) Food poisoning, hepatitis A, influenza, common cold, roundworm, and threadworm common symptoms are

- (a) Poor hygiene
- (b) Personnel hygiene
- (c) Public health
- (d) None of the above

(xvii) Which year of Primary Health Centre to be revised

- (a) 2012
- (b) 2011
- (c) 2010
- (d) 2005

(xviii) ..... is linked to transmission of diseases such as cholera, diarrhea.

- (a) Poor Hygiene
- (b) Poor sanitation
- (c) Both a & b
- (d) None of the above

(xix) Water soluble vitamins are:

- (a) Vit.A & C
- (b) Vit.B & C
- (c) None of the above
- (d) Vit.B

(xx) Vitamin B<sub>7</sub> complexes called as

- (a) Niotin
- (b) Biotin
- (c) Coitin
- (d) None of the above

#### Part-B

**Q.2 Long answer questions.**

**[10x2 = 20 Marks]**

**Note : Attempt any two questions. Each question carries 10 marks.**

- 1) What are the different avoidable habits for the health & hygiene point of view?
- 2) What do you mean by social and health education with respect to vitamin & nutritional deficiencies?
- 3) What is the concept of health and disease? Describe in detail.

#### Part-C

**Q.3 Short answer questions.**

**[5x7 = 35 Marks]**

**Note : Attempt any seven questions. Each question carries 5 marks.**

- 1) Describe HIV control Program.
- 2) Give a note on national leprosy control program.
- 3) Give a short note on any one of given below-
  - i) WHO
  - ii) IDSP
- 4) Give a principle of prevention and control of ebola virus.
- 5) Give a short note on any one of given below-
  - i) Dengue
  - ii) Diabetes mellitus
- 6) What is the role of WHO in Indian national health Program?

- 7) Describe Universal Immunization Program.
- 8) Discuss about integrated disease surveillance program.

Enrollment No.....

**Bachelor of Pharmacy**  
**Eighth Semester Main Examination, June-2021**  
**Pharmaceutical Regulatory Science [BP804ET]**

**Time: 3:00 Hrs**

**Max Marks 75**

**Note : (i) All parts of the question paper are compulsory.**

**(ii) All question of each part to be attempt at one place.**

**Part-A**

**Q.1 Multiple choice questions- [1x20 = 20 Marks]**

- (i) Which of the following is regulatory authority of Australia
  - (a) Pharmaceutical and Medical Devices Agency
  - (b) Therapeutic Goods Administration
  - (c) Medicines and Healthcare Products Regulatory Agency
  - (d) Central Drug Standard Control Organization
- (ii) What is a synonym/description for the Phase 4 trials?
  - (a) Post Marketing Surveillance
  - (b) Pre Marketing Surveillance
  - (c) Pre FDA Approval
  - (d) Post FDA Approval
- (iii) What is the term for the process that is used to prove that a drug is safe and effective in treating specific conditions in certain patient populations?
  - (a) Drug discovery
  - (b) Preclinical development
  - (c) The patent process
  - (d) Clinical development
- (iv) At the end of the study, what happens to the case report forms (CRFs)?
  - (a) The CRF data is compiled and submitted to the FDA in the IND.
  - (b) The CRF data is aggregated by an external party if the trial was double blinded to assess the drug's safety and efficacy.
  - (c) The CRF data is aggregated and analyzed to assess the drug's safety and efficacy.
  - (d) The CRF data is compiled and submitted to Regulatory Affairs
- (v) On what does Phase 3 trials test?
  - (a) Healthy human volunteers
  - (b) Widespread differentiated population
  - (c) People with the target disease/condition
  - (d) Large-scale tests in people with the target disease/population
- (vi) On what does Phase 1 clinical testing test?
  - (a) Healthy human volunteers
  - (b) Widespread differentiated population
  - (c) People with the target disease/condition
  - (d) Large-scale tests in people with the target disease/population

- (vii) What is the purpose of pre-clinical testing?
- To verify that a drug is sufficiently safe and effective to be tested in humans.
  - To undergo preliminary testing in healthy humans to monitor the effects of the drug.
  - To create a basic outline for the larger scale future tests on a widespread population.
  - A and B
- (viii) Clinical development represents the shift from \_\_\_\_\_ to \_\_\_\_\_.
- Laboratory science to patented research and manufacturing technology
  - Project management responsibilities needed to manage human trials to technology
  - Lead compound to patented therapeutic research
  - Laboratory science to project management responsibilities needed to manage human trials
- (ix) What is the purpose of Phase 1 clinical trials?
- To select a lead compound from a lead series
  - To identify a target population.
  - To establish the safety of administration to humans
  - To test whether the proposed drug actually works
- (x) Which phase in clinical development is the largest investment of both time and money?
- Phase 1
  - Phase 2
  - Phase 3
  - Phase 4
- (xi) On average, it takes \_\_\_\_\_ years to do the discovery research and testing to bring a new drug to the market.
- 6 – 9
  - 9 – 12
  - 12 – 15
  - 15 – 18
- (xii) Which is the primary goal/major milestone of preclinical development?
- Filing an IND application with the FDA
  - Identifying the target population for the lead compound that is being developed
  - Aligning the development process with the strategic aims of the company
  - To determine anticipated revenue
- (xiii) What is NOT a true statement about Phase 4 Trials?
- Phase 4 trials are typically not randomized/placebo controlled
  - Phase 4 trials are typically when the product is finalized and submitted for patent protection
  - Phase 4 trials may include new populations in which to test the drug
  - Phase 4 trials may include new formulations and/or adjusted dosing regimens
- (xiv) An \_\_\_\_\_ contains data which is submitted to FDA for the review and potential approval of a generic drug product.
- NDA application
  - IND application
  - ANDA application
  - None of the above.

- (xv) Once the IND is submitted, the sponsor must wait ----- before initiating any clinical trials.
- (a) 60 Calendar days
  - (b) 30 Working days
  - (c) 30 Calendar days
  - (d) None of the above.
- (xvi) Which of the following is a branch of CDL
- (a) New Delhi
  - (b) Kolkata
  - (c) Faridabad
  - (d) Bangalore
- (xvii) Ministry of Health, Labour & Welfare (MHLW) is the regulatory body of .....
- (a) Japan
  - (b) Brazil
  - (c) Sweden
  - (d) Australia
- (xviii) How long does a drug patent last?
- (a) 5 Years
  - (b) 10 Years
  - (c) 20 Years
  - (d) Patent does not expire
- (xix) Full form of ANDA
- (a) Animal New Drug Application
  - (b) Abbreviated New Drug Application
  - (c) Australian New Drug Application
  - (d) None of These
- (xx) New drug application is submitted for
- (a) Beginning of clinical trail
  - (b) Approval of drug for Market
  - (c) For Phase 1
  - (d) For Preclinical Study

#### **PART-B**

**Q. 2 Short Answer Question (Attempt any 07) [5x7 = 35 Marks]**

- 1) What is the general procedure for export of pharmaceutical product?
- 2) Discuss the requirement of Common Technical Document (CTD).
- 3) Compare the documentation requirements of ANDA and NDA submissions.
- 4) How innovator drug is different from generics drugs?
- 5) Write down the objectives of CDSCO.
- 6) Write down the types of DMF
- 7) Write note on developing Clinical Trial Protocols.
- 8) Write note on Orange Book.

#### **PART-C**

**Q. 3 Long Answer Questions (attempt any 02) [2x10 = 20 Marks]**



- 1) Define clinical trial and explain the different phases of Clinical trials
- 2) Describe in detail new drug approval process along with its documentation requirements.
- 3) What are various modules and requirements of electronic Common Technical Document (eCTD)? Compare it with ASEAN common technical documents (ACTD).

Enrollment No.....

**Bachelor of Pharmacy**  
**Eighth Semester Main Examination, June-2021**  
**Advanced Instrumentation Techniques [BP811ET]**

**Time: 3:00 Hrs**

**Max Marks 75**

**Note : (i) All parts of the question paper are compulsory.**

**(ii) All question of each part to be attempt at one place.**

**Part-A**

**Q.1 Multiple choice questions-**

**[1x20 = 20 Marks]**

1. Most intense peak in mass spectrum is known as .....
  - a) Isotope Peak
  - b) Parent Peak
  - c) Base Peak
  - d) Metastable Peak
2. Coupling constant is ..... between adjacent peaks.
  - a) Distance
  - b) Ratio
  - c) Height
  - d) All
3. In Mass Spectroscopy, ions are separated on the basis of ..... values in a magnetic analyzer.
  - a) Atomic Number
  - b) Atomic Mass
  - c)  $m/z$
  - d) None of the above
4. When a molecule or ion contains odd number of nitrogen atoms, it will have an ..... value of molecular weight.
  - a) Even
  - b) Odd
  - c) Both
  - d) None of these
5. In DTA, chemical reaction gives rise to ..... peak.
  - a) Maxima
  - b) Minima
  - c) Exothermic
  - d) Endothermic
6. MALDI stands for
  - a) Matrix Assisted Laser Desorption/ Ionization
  - b) Mass Associated with Laser Desorption/ Ionization
  - c) Materials of Analytical Lens for Distribution of Ions
  - d) None of the above

7. In Mass Spectroscopy, the quadrapole instruments incorporate the combination of a radiofrequency and .....
- Mass
  - Molecules
  - Atoms
  - Direct Current Field
8. The process of transition from excited state to ground state is called
- Excitation
  - Relaxation
  - Translating stage
  - None of the above.
9. PMR counts number of protons by using ..... rule.
- $2n$
  - $n$
  - $(n+1)$
  - None of the above
10. In DSC, size of sample is
- 50-20 mg
  - 50-20 gm
  - 2-10 gm
  - 2-10 mg
11. The process of ionization not only ionize the molecule but also break the molecule into the.....
- Ions
  - Molecules
  - Fragments
  - None of these
12. The mass analyser is used to sort ions according to their .....
- Weight
  - Height
  - Charge
  - Mass to charge ratio
13. The solvent used for extraction must have ..... Viscosity.
- Low
  - Moderate
  - Denser
  - High
14. Continuous extraction is used when the distribution ratio is.....
- High
  - Low
  - Equal
  - All of the above
15. A small molecule which when combined with a larger carrier such as a protein, can elect the production of antibodies which bind specifically to it (it in the free or combined state) is called as
- Antibody

- b) Antigen
  - c) Hapten
  - d) Radio-labeled isotope
16. Which of the following are the parts of instrumentation of RIA?
- a) Gamma counters
  - b) Scintillation counters
  - c) Both a) and b)
  - d) None of the above
17. Estimation of the expanded uncertainty is based on
- a) Repeatability
  - b) Resolution
  - c) Eccentricity
  - d) All of the above
18. Calibration of UV visible spectrophotometer is conducted by using .....
- a) Potassium chromate
  - b) Potassium dichromate
  - c) Sodium hydroxide
  - d) Quinine sulphate
19. The closeness of test results obtained by that method to the true value. This accuracy should be established across its range, the term is .....
- a) Accuracy
  - b) Precision
  - c) Reproducibility
  - d) Range
20. In NMR spectroscopy, full form of NMR is
- a) Nucleoid Magnet Resources
  - b) Nuclear Magnetic Resonance
  - c) Nucleotides Managing Resonance
  - d) Non mass rate

#### Part-B

**Q. 2 Short Answer Question (Attempt any 07) [5x7 = 35 Marks]**

- 1) Explain chemical shift.
- 2) Write a detailed note on instrumentation of NMR.
- 3) Give a brief note on principle of mass spectroscopy.
- 4) How will you describe different types of analyzers used in mass spectrometer?
- 5) Differentiate DTA and DSC.
- 6) Write in detail about applications of X-Ray diffraction method.
- 7) Enlist the parameters of analytical method validation.
- 8) How will you calibrate flame photometer?

#### Part-C

**Q. 3 Long Answer Questions (Attempt any 02) [2x10 = 20 Marks]**

- 1) Give a detailed note on principle and applications of RIA.
- 2) Discuss factors affecting value of partition coefficient.
- 3) Describe working and instrumentation of GC-MS.