B PHARMA VIII SEM
BIOSTATISTICS AND RESEARCH METHODOLOGY
QUESTION BANK

LONG ESSAYS

1. Explain the measures of central tendency
   Calculate the mean and standard deviation for the following data on systolic BP of volunteers –

Systolic BP(mmHg)	91-100	101-110	111-120	121-130	131-140	141-150
Frequency	08	14	20	26	24	18

2. Explain different types of hypothesis. Explain type I and type II errors, level of significance, P value
3. .Explain the different phases of clinical trials.
4. Discuss the protocol for an experimental study design.
5. Explain 't' test. Find if there is statistical significance in the serum digoxin level in the given data:- Critical value= 2.31($p< 0.05$)

Serum digoxin level(mcg/ml)	1	2	3	4	5	6	7	8	9
After4 hrs	1.0	0.9	1.0	1.3	1.0	1.3	0.9	1.1	1.0
After 8 hrs	1.0	0.7	1.0	1.2	0.9	1.3	0.8	1.0	1.0

6. What are measures of dispersion? Explain their significance with suitable examples.
7. Explain the various phases of clinical trials.
8. Explain regression analysis and its applications in stability testing of pharmaceuticals.
9. Explain the measures of dispersion. Calculate mean, variance and standard deviation for the given data:-

Height(cm)	135-140	141-145	146-150	151-155	156-160	161-165	166-170
Frequency	08	12	18	22	20	14	10.

10. Describe the different measures of central tendency. Calculate mean and standard deviation for the given data on mid arm circumference(cm) of 16 children –
    14, 12, 13, 10, 11, 13, 14, 12, 12, 11, 10, 13, 12, 11, 10, 14
11. Explain types of observational study designs.
12. Explain with suitable examples regression analysis and standard error of regression.
13. Explain null and alternate hypothesis, type I and type II errors, confidence interval.
14. Explain chi square test. From the following data, test whether prevalence of scabies is significant in two different genders (critical value=10.83, p,0.001) :-

Gender	Number with scabies	Number with out scabies	Total
Male	1173	10410	11583
Female	547	7640	8187
Total	1720	18050	19770

15. What is hypothesis? What are different types of hypothesis? Explain how you will formulate a hypothesis with a suitable example
16. What is QbD, Why are DOE essential in a QbD development process?
17. What are the measures variability? What is their statistical significance
18. Discuss different types of observational clinical studies in detail.
19. Discuss various steps involved in testing the significance of single mean and difference between two means (independent samples) in small samples using Student's t- test.
20. Classify different types of data, explain any three measures of dispersion with example.
21. Describe briefly the different interventional study designs
22. Explain the hypothesis testing of non-parametric data
23. Describe the various types of measures of dispersion and their significance.
24. Discuss briefly about determination of sample size for simple comparative experiments and for confidence interval of specific width.
25. Explain the hypothesis testing of non-parametric data
26. How is QbD based product development better. Explain the steps in involved in it.
27. How will you design a clinical study methodologically? Explain briefly.
28. What is hypothesis? What are different types of hypothesis? Explain how you formulate the hypothesis with a suitable illustration.
29. Discuss about the hypothesis testing of parametric data.

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SHORT ESSAYS

1. Explain types of correlation and correlation coefficient. Give suitable examples.
2. Define probability and explain its significance in statistical inference with examples.
3. What are measures of dispersion? Explain.
4. Explain ANOVA and its applications.
5. Discuss different methods of sampling.
6. Explain the graphical methods of representing quantitative data.
7. Discuss the applications of EXCEL and SPSS programmes in statistical analysis.
8. What are non-parametric tests? Explain chi square test-Goodness of fit test.
9. Explain the types and advantages of factorial design in formulation development.
10. Explain correlation, types of correlation and its applications.
11. Explain null hypothesis, type I and type II errors.
12. Discuss with examples measures of central tendency.
13. Discuss the sampling methods in research study.
14. Explain probability and its significance in statistical analysis.
15. Explain regression analysis to assess the influence of independent variable on continuous variable.
16. Explain the hypothesis testing using one way of ANOVA.
17. Describe the various of graphical methods of representing quantitative data.
18. Explain a typical experimental study design.
19. Define and explain correlation with examples.
20. Explain student‘t’ test and its applications.
21. Explain types of observational study designs.
22. Explain ANOVA and its significance.
23. Discuss null hypothesis, type I and type II errors.
24. Explain the application of factorial design in pharmaceutical product development.
25. Explain with examples- Histogram, Pie chart.
26. Describe the sampling techniques in research study.
27. Discuss Wilcoxon Rank Sum test and Mann Whitney U test.
28. Explain type I and type II errors.
29. Discuss the methods of sample size calculation in comparative studies.
30. Explain Karl Pearson’s coefficient of correlation with examples.
31. Explain chi square test for Goodness of fit.
32. Discuss the applications of SPSS and SAS in research study.
33. Explain one way ANOVA and the assumptions in one way ANOVA.
34. Briefly describe the different distribution patterns of data.
35. Discuss- Histogram, Bar diagram.
36. Explain phases of clinical trial.
37. Define ‘t’ test. Explain the different situations where paired and unpaired ‘t’ tests applied
38. Explain the different measures of dispersion of data**.**
39. Explain ANOVA and its applications
40. Explain the pharmacokinetic applications of regression analysis.
41. Define and explain probability and its significance in statistics.
42. Define and explain experimental study designs.
43. Discuss the methods of sampling in research study.
44. Explain correlation coefficient and types of correlation.
45. Discuss the applications of SPSS and MINITAB in data analysis.
46. Discuss observational studies.
47. Describe variance and standard error of mean with suitable example.
48. List the elements that need to be incorporated in a clinical study protocol?
49. Explain the concept of DOE
50. Describe how Mean is the most appropriate measure of centrality with suitable example?
51. Explain linear regression? How is it applied for pharmaceutical sciences.
52. Explain the statistics of stability testing of pharmaceutical products
53. Explain the concept of design space in QbD
54. Discuss the general rules for constructing and labeling a graph? b) Describe the construction of a semi-logarithmic graph with an example?
55. How is central tendency measured?

56. What are general rules for constructing and labeling a graph? Write a note on semi-logarithmic plot with an example.
57. Write notes on randomization and objectives of clinical studies.
58. What characteristics of data can be represented by a) Histogram b) Pie chart c) Semi-logarithmic plots
59. How will test hypothesis for ordinal data.
60. Explain chi square test
61. Explain the concept of Fractional factorial Design
62. Compare and contrast Nonparametric and Parametric data
63. Explain the concept of Central Composite Design
64. Explain report writing in research methodology.
65. Explain the hypothesis testing of non-parametric data
66. Describe variance and standard error of mean with suitable example.
67. What are the underlying assumptions of one way ANOVA? Explain under what circumstances ANOVA is the most preferred type of statistical data analysis?
68. Discuss the general rules for constructing and labeling a graph? b) Describe the construction of a semi-logarithmic graph with an example?
69. Compare and contrast Nonparametric and Parametric data
70. What are the underlying assumptions of one way ANOVA? Explain under what circumstances ANOVA is the most preferred type of statistical data analysis?
71. Explain Fractional Factorial Design
72. Role of QbD in Pharmaceutical Development
73. Classify different types of data. Explain any three measures of dispersion with examples.
74. Classify and list the tests used for hypothesis testing of parametric data
75. Classify and explain different types of t- tests.
76. Explain Pearson's correlation &Spearmann's correlation.
77. Explain Wilcoxan signed rank test and Mann Whitney U test.
78. Explain in detail about cross-over and parallel clinical study design.
79. Classify types of data. Give an outline of testing hypotheses for different types of data
80. What are Mixture Designs? List their applications
81. Explain linear regression? How is it applied for pharmaceutical sciences?
82. Explain about standard deviation and variance.
83. Explain Pearson's correlation &Spearmann's correlation.
84. List the pharmaceutical applications of Student's t test.
85. List the pharmaceutical applications of Student's t test.
86. Distinguish between parametric and non-parametric tests. For what type of data is Chi Square test performed?
87. What is underlying assumptions of one way ANOVA? If these assumptions are not fulfilled which alternative non-parametric test do you suggest?
88. What is QbD. List the experimental designs used in QbD
89. Explain how computers can be used for patient record database management in hospital pharmacy

SHORT ANSWER

1. Multiple regression.
2. One tailed and Two tailed tests.
3. Pharmaceutical examples for optimization techniques.
4. Degrees of freedom.
5. Standard error of mean and its significance.
6. Two methods of sample size calculation in research study.
7. Examples of application of regression models in stability testing.
8. Wilcoxon Rank Sum test.
9. Normal distribution of data.
10. Types of Observational study designs.
11. Sample size calculation for confidence interval.
12. Power of a study.
13. Pharmaceutical examples for data analysis using SPSS.
14. Factorial design.
15. Degrees of freedom.

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16. Report writing in research study.
17. Assumptions in chi square test.
18. Confidence interval.
19. Characteristics of Normal distribution data.
20. Applications of nonparametric tests.
21. chi square test.
22. Power of a study.
23. Confidence interval
24. Probability.
25. Applications of SAS
26. Standard error of mean
27. . Features of normal distribution pattern.
28. Optimization techniques
29. Report writing in research study.
30. When is median more important than mean as a measure of central tendency
31. Degrees of freedom**.**
32. 2^2 and 2^3 designs.
33. Power of a study.
34. Probability.
35. Applications of student't' test.
36. Standard error of mean.
37. One tailed and Two tailed tests.
38. Applications of non-parametric tests.
39. Confidence interval.
40. Pharmaceutical examples of optimization techniques.
41. Characteristics of normal distribution**.**
42. Standard error of mean.
43. Histograms.
44. Report writing in research study.
45. Wilcoxon Rank Sum test.
46. Differentiate between sample and population parameter.
47. Power of study.
48. Descriptive and interferential statistics.
49. Classification of clinical study designs.
50. Factorial design.
51. Power of study
52. Confidence interval
53. Define blinding in clinical study.
54. Differentiate SD and SEM.
55. Difference between nominal and ordinal type of data.
56. Define scatter plots.
57. p-value
58. Mann Whitney U tests.
59. Advantages of Design space
60. Explain one way analysis of variance.
61. Confidence interval
62. Classification of clinical study designs
63. Power of study.
64. Define coefficient of variation.
65. Comparison of means between three or more distinct/independent groups which parametric and non-parametric test can be used in inferential statistics?
66. Sign test.
67. Pearson's Correlation.

68. Standard Error of Mean
69. Advantages of Data visualization methods
70. Central composite design
71. Define bias in clinical study.
72. Role of sample size in calculation of confidence interval
73. Characteristics of normal distribution
74. Advantages and disadvantages Pie charts.
75. Explain: Range, Interquartile range and Variance
76. Standard Error of Mean
77. One tailed and two tailed tests.
78. Control Space
79. Inclusion & exclusion criteria
80. Define histogram
81. Define discrete and continuous variables.
82. Pie charts.
83. Types of correlation.
84. What is Control Space
85. Difference between ANOVA and student t test.
86. What factors qualifies mode to be the best measure of central tendency?
87. Define α and β error.
88. Degree of freedom.
89. Classify observational and experimental studies.
90. What is interventional study?
91. List the characteristics of observational studies.
92. Define coefficient of variation.
93. Characteristics of normal distribution.
94. Define semi logarithmic plots.
95. Application of Post Hoc tests
96. Type I and Type II errors in hypothesis testing.
97. Design Space
98. Degrees of freedom.
99. Define surrogate & direct end point.
100. Relationship between sample size and power of the study.

BLUE PRINT OF MODEL QUESTION PAPER

BP801T. BIOSTATISITCS ANDRESEARCHMETHODOLOGY

TIME: 3 HOURS MAX. MARKS: 75

Unit No	Hours	Must know			Desirable to know			Weightage of marks
		LE (10X3)	SE (5X8)	SA (2X5)	LE (10X0)	SE (5X1)	SA (2X5)	
Unit-I	10	1	2	1	_		2	22
Unit-II	10	1	2	2	_	1	1	22
Unit-III	10	1	2		_		1	19
Unit-IV	08	-	1	1	_		1	16
Unit-V	07	-	1	1	_	-		16
Total	**45**	**30**	**40**	**10**	**-**	**5**	**10**	**95**
			80			**15**		**95**