

Rajiv Gandhi University of Health Sciences, Karnataka  
4 Pharm D & 1 PB | QP CODE: 2870 /2886 - Biostatistics & Research Methodology

# Question Bank

## Unit 1 – Research Methodology

### Long Essay 10 M

1. Describe briefly the different interventional study designs.
2. Explain different observational study designs.
3. What are case studies? Why are they conducted, explain them in detail.
4. How will you design a clinical study methodologically? Explain briefly.
5. Explain in detail the Clinical Trial Design. Classify its designs. Explain graphically the parallel and crossover study designs.
6. Write notes on a) randomization, b) objectives c) direct and surrogate end point in Clinical study. (5+2+3)
7. Discuss briefly about designing the methodology for clinical studies B) Describe how a sample size is determined for simple comparative experiments. (5+5)
8. Discuss briefly about determination of sample size for simple comparative experiments and for confidence interval of specific width.
9. Discuss in detail about various clinical studies designs.
10. Describe various clinical study designs in detail? Write about the importance of Biostatistics?
11. What are case studies, Explain briefly.
12. Discuss different types of observational clinical studies in detail.
13. Discuss the designing methodology in clinical research.

### Short Essay 5 M

1. Explain report writing in research methodology
2. Explain sample size estimation for simple comparative studies
3. Discuss observational studies
4. Advantages and disadvantages of Randomized control clinical trials
5. Explain cohort and cross sectional studies
6. How do you design a parallel group study?
7. Explain the clinical trial crossover design and its advantages.
8. What is a cohort study? When is it done and list its types and advantages

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9. What are case control studies? And how will you design one?
10. List the elements that need to be incorporated in a clinical study protocol?
11. What are "retrospective designs" in observational case studies, list its advantages
12. Explain the clinical trial crossover design and its advantages.
13. List the elements that need to be incorporated in a clinical study protocol?
14. How do you design a parallel group study?
15. Give a detailed account of sample size determination.
16. Explain report writing and presentation of data.
17. Write short notes on observational studies.
18. Explain power of a study.
19. Discuss different types of observational clinical studies .
20. Explain in detail about cross-over and parallel clinical study design.
21. Write a note on randomization in clinical study.
22. What is sample size? Discuss briefly about determination of sample size for simple comparative experiments with suitable examples.
23. Write notes of interventional studies.
24. Explain about the steps involved in research design.
25. Role of sample size in the calculation of confidence interval.
26. Write note on Randomization and objectives of clinical studies.

**Short Notes 2 M**

1. Inclusion & exclusion criteria
2. Power of study
3. Classify Observational and experimental studies
4. Compare clinical trials and cross sectional studies
5. Cross sectional designs
6. Confidence interval
7. Importance of sample size determination in research
8. Role of sample size in calculation of confidence interval
9. list the characteristics of observational studies
10. What is blinding in clinical study.
11. Define bias in clinical study.
12. Define power of a study?
13. What is interventional study?

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14. Relationship between sample size and power of the study.
15. What is case study
16. Define Cohort study.
17. What is sample size?
18. Classification of clinical study designs.
19. What is carry-over effect?
20. Define cross sectional study.
21. Define surrogate & direct end point.
22. Importance of control group in clinical study.
23. Inclusion and exclusion Criteria in clinical study.

**Unit 2- Biostatistics****Long Essay 10 M**

1. Describe the methods of measurement of central tendency
2. Describe the various types of measures of dispersion and their significance.
3. What do you understand by measures of central tendency? Describe the types of measures and their characters.
4. Explain different measures of central tendency with the help of suitable examples. Give reasons why they are called as measures of central tendency.
5. Classify types of data and explain different measures of central tendency with the help of suitable examples.

**Short Essay 5 M**

1. Explain different methods of describing data using the measures of central tendency.
2. Explain about standard deviation and variance.
3. Explain median and mode.
4. Classify different types of data, explain any three measures of dispersion with example.
5. Describe variance and standard error of mean with suitable example.
6. Describe how Mean is the most appropriate measure of centrality with suitable example?
7. Why is central tendency measured?
8. Write note on standard deviation and standard error of mean with suitable example.
9. What is coefficient of variation? Explain its importance over standard deviation with an illustration.

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10. In routine diagnostic investigation the following results were obtained: 3, 5, 7, 11, 14 and 57. Compute the mean, standard deviation and coefficient of variation of the following data,

**Short Notes 2 M**

1. Differentiate SD and SEM.
2. Difference between nominal and ordinal type of data.
3. Characteristics of normal distribution.
4. Define coefficient of variation.
5. Define median and mode.
6. Define quantitative and qualitative variables.
7. Define the scope of descriptive and inferential statistics.
8. Define discrete and continuous variables.
9. What factors qualify mean to be the best measure of central tendency?
10. What factors qualify median to be the best measure of central tendency?
11. What factors qualify mode to be the best measure of central tendency?

**Unit 3- Data Graphics****Short Essay 5 M**

1. What characteristics of data can be represented by a) Histogram b) Pie chart c) Semi-logarithmic plots
2. What are the general rules for constructing and labeling a graph? b) Write a note on semilogarithmic plot.
3. How histograms, scatter plots, and semi-logarithmic plots are useful in presenting the data?
4. Describe the construction of any three types of graphical representation of statistical data with suitable examples.

**Short Notes 2 M**

1. Define histogram
2. Advantages and disadvantages of Pie charts.

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3. Define scatter plots.
4. Define semi logarithmic plots.
5. Applications of Semi Logarithmic plots.
6. What are the disadvantages of pie chart?
7. General rules for constructing and labeling a graph.
8. Define scatter plots and semi logarithmic plots.
9. Define data graphics.
10. Pie chart

**Unit 4 - Basics of testing of hypothesis****Long Essay 10 M**

1. Discuss about the hypothesis testing of parametric data
2. Explain the hypothesis testing of non-parametric data
3. Explain Hypothesis Testing (HT) in detail. Discuss the clinical versus the statistical significance of HT.
4. What is hypothesis? What are different types of hypothesis? Explain how you will formulate a hypothesis with a suitable example.
5. Define correlation and regression. What are the different measures of correlation? Explain which measures are used for computation of correlation.
6. What is hypothesis? What are different types of hypothesis? Explain how you formulate the hypothesis with a suitable illustration.
7. Discuss various parametric tests used to determine level of significance of a clinical study.
8. Discuss various steps involved in testing the significance of single mean and difference between two means (independent samples) in small samples using Student's' test.
9. Explain the following: Null hypothesis, level of significance, power of test, p value.

**Short Essay 5 M**

1. Explain  $\alpha$  &  $\beta$  errors in hypothesis testing.
2. Classify and explain the measures of central tendency
3. Compare and contrast Nonparametric and Parametric data
4. Classify and explain the tests used for hypothesis testing of parametric data

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5. Explain linear regression? How is it applied for pharmaceutical sciences
6. Explain accounting and general ledger systems
7. Explain Pearson's correlation & Spearmann's correlation.
8. Define (a)  $\alpha$  error and  $\beta$  error (b) Define confidence interval and (c) power of the test
9. What are the underlying assumptions of one way ANOVA? Explain under what circumstances ANOVA is the most preferred type of statistical data analysis?
10. Define Correlation and regression. What are the different measures of Correlation? Explain which measure is used for computing correlation between two quantitative variables.
11. Distinguish between parametric and non-parametric tests. For what type of data is Chi Square test performed?
12. Explain linear regression? How is it applied for pharmaceutical sciences
13. Write a note on null and alternate hypothesis
14. Explain Wilcoxon's signed rank test and Sign test
15. Write briefnote on statistical software of SPSS, Epi info and SAS.
16. Note on Correlation and Regression and their applications
17. Classify and explain different types of t tests and explain them.
18. Explain Wilcoxon signed rank test and Mann Whitney U test.
19. Explain the uses of chi-square test giving suitable examples
20. Describe analysis of variance by stating related assumptions. Explain why Student's t-test cannot be applied where ANOVA has to be applied.
21. What is ANOVA? Explain the method of one way ANOVA.
22. What are underlying assumptions of one way ANOVA? If these assumptions are not fulfilled which alternative non-parametric test do you suggest?
23. What is correlation? Name different types of correlation. Which are the different measures of correlation?
24. What are the assumptions under which chi-square test can be applied to analyze data. For what type of data chi-square test is applied.
25. Explain the need for testing of hypothesis in pharmaceutical research.
26. What is linear regression? How is it useful in pharmaceutical sciences?
27. Explain chi square test
28. List the pharmaceutical applications of Student's t test.
29. Calculate the variance and standard deviation for the following data

|             |        |         |         |         |         |         |         |
|-------------|--------|---------|---------|---------|---------|---------|---------|
| Haemoglobin | 9.1 to | 10.1 to | 11.1 to | 12.1 to | 13.1 to | 14.1 to | 15.1 to |
|-------------|--------|---------|---------|---------|---------|---------|---------|

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|                       |      |      |      |      |      |      |      |
|-----------------------|------|------|------|------|------|------|------|
| value (gm%)           | 10.0 | 11.0 | 12.0 | 13.0 | 14.0 | 15.0 | 16.0 |
| Number of individuals | 11   | 14   | 28   | 22   | 16   | 12   | 8    |

30. Calculate the mean for the following data

|                     |        |         |          |          |          |          |
|---------------------|--------|---------|----------|----------|----------|----------|
| 1 to 6 Age in Years | 1 to 6 | 7 to 12 | 13 to 18 | 19 to 24 | 25 to 30 | 31 to 36 |
| Frequency           | 6      | 11      | 25       | 20       | 15       | 18       |

31. The following is the data on gain in body weight of two groups of young rats (28 to 30 days) maintained on two types of diet (high and low protein). Calculate whether the change in the body weight is observed due to diet or not using unpaired paired student t-test

(Critical value=1.83)

|                                |    |    |     |    |    |     |     |    |     |     |
|--------------------------------|----|----|-----|----|----|-----|-----|----|-----|-----|
| Group A<br>(high protein diet) | 95 | 98 | 101 | 90 | 89 | 105 | 110 | 85 | 100 | 102 |
| Group B<br>(low protein diet)  | 72 | 79 | 80  | 75 | 81 | 78  | 88  | 72 | 73  | 74  |

32. Haemoglobin value (gm%) were estimated before and after the treatment with vitamin B12 in 06 human volunteers. Calculate whether the changes were significant due to drug therapy or not by applying paired t-test. (critical value at 5% level of significance = 2.571)

|                  |      |      |      |      |      |      |
|------------------|------|------|------|------|------|------|
| Before treatment | 12.2 | 11.3 | 14.7 | 11.4 | 11.5 | 12.7 |
| After treatment  | 13.0 | 13.4 | 16.0 | 13.6 | 14.0 | 13.8 |

 33. Determine if there is an association between whooping cough and tonsillectomy in a random sample of 100 children in a school with the following data (critical value = 5.41 at  $P < 0.02$ )

|                  |                |                   |       |
|------------------|----------------|-------------------|-------|
| Group            | whooping cough | No whooping cough | Total |
| Tonsillectomy    | 10             | 15                | 25    |
| No Tonsillectomy | 50             | 25                | 75    |



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|       |    |    |     |
|-------|----|----|-----|
| Total | 60 | 40 | 100 |
|-------|----|----|-----|

34. Find the mean, standard deviation and coefficient of variation for the following blood pressure measurements: 100,98,101,94,104,102,108,108.

35. The following data for blood protein (gm/100ml) were observed for the comparison of two drugs, both drugs being tested on each person in random manner.

| patient | 1   | 2   | 3   | 4   | 5   | 6   | 7   | 8   | 9   | 10  | 11  | 12  |
|---------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Drug A  | 8.1 | 9.4 | 7.2 | 6.3 | 6.6 | 9.3 | 7.6 | 8.1 | 8.6 | 8.3 | 7.0 | 7.7 |
| Drug B  | 9.0 | 9.9 | 8.0 | 6.0 | 7.9 | 9.0 | 7.9 | 8.3 | 8.2 | 8.9 | 8.3 | 8.8 |

Perform statistical test for drug differences at 5% level.

36. It is hypothesized that the difference between two drugs with regard to success rate is zero (i.e. the two drugs are not different). What size sample is needed to show a difference of 20% significant at the 5% level with a  $\beta$  error of 10% (assume that the response rate is about 50% for both drugs & study is a two independent sample design).

37. A tablet is produced with a labeled potency of 100mg. the standard deviation is known to be 10. What size sample should be assayed if we want to have 90% power to detect a difference of 3mg from the target. The test is done at 5% level.

38. A parallel design is used to measure the effectiveness of a new anti-hypertensive drug with one group of patient receiving the drug and the other group receiving the placebo, a difference of 6mm Hg is considered to be of practical significance, the standard deviation is unknown but is estimated as 5 based on preliminary data.  $\alpha$  is set at 5% &  $\beta$  at 10%. How many patients should be used in each group

**Short Notes 2 M**

1. What is Chi-square test?
2. Power of study
3. R values of Correlation
4. Explain: Range, Interquartile range and Variance
5. What is ANOVA.
6. Student's t-test
7. Applications of Student's t-test.
8. Standard Error of Mean
9. Pearson's Correlation
10. p-value



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11. Sign test.
12. What is Type I and Type II errors in hypothesis testing.
13. One tailed and two tailed tests.
14. Mann Whitney U tests.
15. Explain one way analysis of variance.
16. Define Regression. Explain types of regression.
17. Types of correlation.
18. What is linear regression?
19. Define  $\alpha$  and  $\beta$  error.
20. Level of significance.
21. Paired t – test.
22. Wilcoxon rank sum test.
23. Degree of freedom.
24. Confidence intervals.
25. Difference between statistics and parameter
26. Difference between ANOVA and student t test.
27. Differentiate parametric and nonparametric data.
28. Comparison of means between two distinct/independent groups which parametric and non-parametric test can be used in inferential statistics?
29. Comparison of two quantitative measurements taken from the same individual which parametric and non-parametric test can be used in inferential statistics?
30. Comparison of means between three or more distinct/independent groups which parametric and non-parametric test can be used in inferential statistics?

**Unit 5 - Statistical Methods in Epidemiology****Short Essay 5 M**

1. Define Epidemiology. Explain types of epidemiological markers .
2. Write notes on Incidence and prevalence.
3. Write notes on relative and attributed risk.

**Short Notes 2 M**

1. Types of epidemiological markers.
2. How will you calculate Incidence?

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3. Define Relative Risk.
4. Define Attributable Risk.
5. Define Prevalence and Incidence.

## **Unit 6 - Computer applications in pharmacy**

### **Long Essay 10 M**

1. Explain the role of computers in patient medication profiles
2. List the applications of computing systems in hospital pharmacy.
3. Explain the role of computers in Patient medication profiles and Inventory control.
4. Elucidate the computer use in hospital pharmacy

### **Short Essay 5 M**

1. Explain how computers can be used for patient record database management in hospital pharmacy
2. Explain accounting and general ledger systems
3. Explain the uses of computers in drug information retrieval and storage.
4. Computer medication order entry.
5. Explain Drug information retrieval and storage.
6. Write the use of computers for pharmaceutical care in community pharmacy.
7. What is inventory control? Explain the role of computers in inventory control.
8. Write a note on computer applications in prescription dispensing process.
9. Write out the patient record database management.
10. Advantages of Computerized Medication Order Entry.
11. Uses of Computers in Pharmaceutical care

### **Short Notes 2 M**

1. Inventory control
2. Computerized literature retrieval
3. Computerized prescription dispensing.
4. Advantages of patient records database management.