

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
Ph.D. COURSE WORK EXAMINATION (REGULAR) – WINTER 2025

Subject Code: PHD2401

Date: 12/10/2025

Subject Name: Research Methodology_ Pharmacy & Biotechnology

Time: 01.30 PM – 04.30 PM

Total Marks: 70

Instructions:

1. Attempt all questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

- Q.1 (a)** Answer the following briefly: **10**
- i) If degrees of freedom increase, what happens to the shape of the Student's t-distribution?
 - ii) Give one real-world example each where (i) binomial distribution and (ii) Poisson distribution is more appropriate.
 - iii) A clinical trial shows $p = 0.07$ at 5% significance level. Interpret this result in terms of null hypothesis.
 - iv) Why are non-parametric tests preferred when data deviate strongly from normality? Support with an example.
 - v) Differentiate between correlation and regression by giving an example of when each would be applied.
- (b)** Outline the essential sections that should be included in a research project proposal. Write a brief research proposal (in about 150-200 words) focusing on the development of the herbal formulation for Diabetes management. And also name any two major funding agencies that support biomedical or pharmaceutical research in India. **10**
- Q.2 (a)** Answer the following in detail: **10**
- i) Compare Kline and McClintock methods for uncertainty estimation. In what scenario would one method be preferred over the other, and why? Illustrate with a practical example.
 - ii) Design a short questionnaire to study smartphone addiction among teenagers. Explain how you would validate it and why validation is critical.
- (b)** Answer the following in detail: **10**
- i) Discuss the importance of literature review in research. How does it guide the formulation of a research problem?
 - ii) Enlist various types of research design. Describe in detail one qualitative and one quantitative research design in detail.
- Or**
- (a)** Answer the following briefly: **10**
- i) Write three main domains of the COREQ checklist.
 - ii) What is thematic map? Name any two types of thematic map.
 - iii) What are characteristics of well formulated research problem?
 - iv) Enlist different sources of literature.
 - v) Give a research example where inductive reasoning could lead to a misleading conclusion. Explain briefly.

- (b) Describe the role of 'claims' in a patent application and explain how they determine the scope of protection. Support your answer with a relevant case study. 10
- Q.3 (a) Compare and contrast the structure of a research report versus a thesis. Explain the importance of including both figures and tables in a research report 05
- (b) A pharmaceutical company develops a new formulation of an existing drug. Explain whether it qualifies for a patent and justify your answer using the conditions for patentability. 05
- Q.4 (a) Answer the following: 05
- i) Which chart is ideal for comparing the market share of 5 drug companies?
 - ii) Which chart would best track the timeline of a clinical trial?
 - iii) Which chart is used in pharmacokinetics to depict AUC?
 - iv) If you wanted to understand which 20% of manufacturing defects cause 80% of quality issues, you should use which type of chart?
 - v) Which visualization would best illustrate the correlation between molecular weight and logP of 50 NCEs (New Chemical Entities)?
- (b) Answer the following: 05
- i) Differentiate between trademark and geographical indication with suitable examples.
 - ii) What is one-way ANOVA? Discuss its assumptions and when it is appropriate to use instead of multiple t-tests.
- Q.5 (a) Answer the followings: 05
- i) Scientists create a new vaccine to combat a specific strain of influenza. They conduct extensive lab tests and clinical trials to ensure safety and efficacy. Once approved, the vaccine is mass-produced and distributed globally, leading to a significant reduction in influenza cases and related deaths. What type of research is this **based on outcome**?
 - ii) Researchers survey 500 college students about their exercise habits and mental health. Using statistical analysis, they find that students who exercise more frequently tend to have lower levels of stress and anxiety. This demonstrates a correlation between exercise and mental health among college students. What type of research is this **based on Process**?
 - iii) A pharmaceutical marketing team conducted ethnographic research to understand how consumers interact with over-the-counter medications in their daily lives. Researchers observed and documented consumer behavior in real-world settings. What type of **process research** is this?
 - iv) Researchers have developed predictive models to assess an individual's risk of developing heart disease. This model could then be used by healthcare providers to assess a patient's risk of developing heart disease within a certain time frame, such as the next 10 years. By identifying individuals at higher risk, doctors can implement preventive measures such as lifestyle changes, medication, or closer monitoring to reduce the likelihood of heart disease occurrence. What type of research is this **based on purpose/ depth of scope**?

- v) Chemists analyze the chemical composition of a new substance, like a plant extract, using techniques such as chromatography or spectroscopy. This helps them understand its properties and potential uses. **Based on purpose** what type of research is this?
- (b) Explain the purpose of the Student's t-test. Differentiate between independent samples t-test and paired samples t-test with examples. 05

