

Seat No.: _____

Enrolment No. _____

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

Subject Code: PHD2301

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) Discuss COREQ guidelines in reporting qualitative studies citing appropriate case study. 10
- (b) You are to write a project proposal to a funding agency. Based on your proposed PhD work, write down the key elements which should be mentioned in your proposal 10
(Note: Divide your answer to include, background, Novelty, need for present work, objectives, Plan of work, methodology, budget, expected outcome- future prospects, and 2 experts from the field for reviewing the proposal).
- Q.2**
- (a) The national drug regulatory authority wants to assess physicians' awareness and prescribing patterns of a newly approved class of antibiotics to combat antimicrobial resistance. The target population is all practicing physicians in the country. They plan to administer a survey. 10
- a) Identify a feasible sampling technique for this nationwide study and justify your choice. (3 marks)
- b) Draft three different types of questions (e.g., multiple-choice, Likert scale, ranking) that you would include in the questionnaire to effectively measure awareness, attitudes, and prescribing behavior. (3 marks)
- c) Explain two key principles of questionnaire design that must be followed to ensure the data collected is valid and reliable from a diverse physician population. (3 marks)
- d) What is one major limitation of using a self-administered survey for this purpose? (1 marks)
- (b) A biotech company, "BioHeal," is testing a new biologic drug, "OsteoStrong," for increasing bone density in postmenopausal women with osteoporosis. They conduct a randomized controlled trial with 200 patients (100 on OsteoStrong, 100 on a placebo). After 12 months, they use an independent samples t-test to compare the mean increase in bone mineral density (BMD) between the two groups ($\alpha=0.05$). The analysis yields a p-value of 0.07 10
- a) State the null hypothesis (H_0) and the alternative hypothesis (H_1) for this test. (3 marks)
- b) Interpret the p-value of 0.07. What should the company conclude about OsteoStrong's efficacy based on this result alone? (3 marks)

c) Explain the concept of a Type II error in this specific scenario. What factor related to the company's product development would be impacted by a Type II error? (4 marks)

or

(a) GenoLabs Ltd. is launching a new targeted therapy for lung cancer with a specific genetic marker. They want to evaluate the drug's real-world effectiveness. The administration needs to know not only the overall survival rates (quantitative) but also the patients' quality of life and experiences with side effects (qualitative) compared to standard chemotherapy. 10

a) Identify the most appropriate research design for this post-market study and justify your choice. (3 marks)

b) Outline a quantitative method to measure the drug's effectiveness. (3 marks)

c) Outline a qualitative method to understand patients' quality of life. Which specific qualitative design would be suitable and what would be the key steps in data analysis? (4 marks)

(b) Dr. Patel is beginning her PhD thesis on "The role of gut microbiota in modulating the efficacy of immunotherapy in cancer patients." She has spent months reviewing existing literature. 10

a) Describe the purpose of the literature review in Dr. Patel's research. (3 marks)

b) Outline a systematic strategy she should use to organize and synthesize the literature from various databases. (3 marks)

c) After her review, she finds that most studies have been conducted on Western populations, with little data on South Asian populations where dietary patterns are significantly different. Explain how this finding helps her identify a clear research gap and formulate her research problem. (4 marks).

Q.3 (a) Explain research onion framework using suitable case study. 05

(b) You are a researcher at a national institute applying for a grant to study the "Pharmacogenomics of antidepressant drug response in a South Asian population" over 24 months. The study will involve genetic testing and clinical assessments. 05

a) Create a basic work plan or time-frame for your 24-month project, dividing it into major phases (e.g., ethical approval, participant recruitment, lab analysis, data interpretation, report writing). (3 marks)

b) List four key budget heads for this project. (2 marks)

Q.4 (a) List two major purposes of literature review in research. 05

(b) Explain Kruger's criteria for conducting focus group interview 05

Q.5 (a) Explain the difference between discrete and continuous data with pharmaceutical examples. 05

(b) Discuss priori and posteriori probabilities citing suitable examples 05
