

**GUJARAT TECHNOLOGICAL UNIVERSITY**  
**PHARM.D YEAR-4/ PHARM.D (PB) YEAR-1 EXAMINATION – WINTER - 2024**

**Subject Code: 848804/818904****Date: 10-12-2024****Subject Name: Biostatistics & Research Methodology****Time: 10:30 AM TO 1:30 PM****Total Marks: 70****Instructions:**

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

- Q.1** (a) Provide a comparison of crossover and parallel designs. **06**  
 (b) Give an overview of various types of clinical study designs. **04**  
 (c) Comment with reasons: Power depends on both the size of the sample and the degree of variability. **04**
- Q.2** (a) Calculate the standard deviation of the following sample data 101.8, 103.2, 104.0, 102.5, and 103.5. **06**  
 (b) For the following blood pressure measurements: 100, 98, 101, 94, 104, 102, 108 and 108 calculate coefficient of variation. **04**  
 (c) List three experiments whose outcomes will result in each of the following kinds of variables: (a) Continuous variables (b) Discrete variables **04**
- Q.3** (a) Describe salient consideration for proper construction and labeling of the typical rectilinear graph with a suitable example. **06**  
 (b) Construct a Semilogarithmic graph to find the half-life from following data. **04**  
 (Assume first order rate reaction)
- | Time after injection, t (hr) | Blood level, C (g/mL) |
|------------------------------|-----------------------|
| 0                            | 20                    |
| 1                            | 10                    |
| 2                            | 5                     |
| 3                            | 2.5                   |
| 4                            | 1.25                  |
- (c) Define null hypothesis and alternate hypothesis with example. **04**
- Q.4** (a) A tablet is produced with a labeled potency of 100 mg. 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 3 mg from the target? The test is done at the 5% confidence level. **06**  
 (b) Define Sample. Brief out various methods of sample size determination. **04**  
 (c) What are different types of errors and explain one with example. **04**
- Q.5** (a) It is hypothesized that the difference between two drugs with regard to success rate is 0 (i.e., the drugs are not different). What size sample is needed to show a difference of 20% significant at the 5% level with a error of 10%? (Assume that the response rate is about 50% for both drugs, a conservative estimate.) The study is a two independent samples design (parallel groups). **06**  
 (b) What is randomization? Discuss any one method of randomization. **04**  
 (c) Define following terminologies: **04**  
 i) Incidence ii) Prevalence iii) Relative risk iv) Attributable risk

- Q. 6 (a)** In a test for pain relief, two drugs are compared where the outcome is 0, 1, or 2, where 0 = no relief, 1 = partial relief, 2 = complete relief. With drug A, 50 had a score of 0, 50 scored 1, and 75 scored 2. With drug B, 20 had a score of 0, 60 scored 1, and 60 scored 2. Use a Chi-square test to compare drugs A and B. How would you interpret a significant effect? **06**
- (b)** Introduce advantages of computerized literature retrieval. **04**
- (c)** Write a note on application of computers in inventory control. **04**
- Q.7 (a)** Dissolution is compared for three experimental batches with the following results (each point is the time in minutes to 50% dissolution for a single tablet): **06**  
 Batch 1: 15, 18, 19, 21,23, 26  
 Batch 2: 17, 18, 24, 20  
 Batch 3: 13, 10, 16, 11,9  
 Is there a significant difference among batches?
- (b)** Give advantages and limitations of computerized prescriptions **04**
- (c)** Discuss role of computers in management of Adverse drug reactions **04**

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**For Reference**

**For Chi Square values refer following table**

**Table IV.5** Chi-Square Distributions

Degrees of Freedom	Probability								
	0.01	0.025	0.05	0.1	0.2	0.8	0.9	0.95	0.99
1	6.634897	5.023886	3.841459	2.705544	1.642375	0.064185	0.015791	0.003932	0.000157
2	9.21034	7.377759	5.991465	4.60517	3.218876	0.446287	0.210721	0.102587	0.020101
3	11.34487	9.348404	7.814728	6.251388	4.641628	1.005174	0.584374	0.351846	0.114832
4	13.2767	11.14329	9.487729	7.77944	5.988617	1.648777	1.063623	0.710723	0.297109
5	15.08627	12.8325	11.0705	9.236357	7.289276	2.342534	1.610308	1.145476	0.554298
6	16.81189	14.44938	12.59159	10.64464	8.55806	3.070088	2.204131	1.635383	0.87209
7	18.47531	16.01276	14.06714	12.01704	9.80325	3.822322	2.833107	2.16735	1.239042
8	20.09024	17.53455	15.50731	13.36157	11.03009	4.593574	3.489539	2.732637	1.646497
9	21.66599	19.02277	16.91898	14.68366	12.24215	5.380053	4.168159	3.325113	2.087901
10	23.20925	20.48318	18.30704	15.98718	13.44196	6.179079	4.865182	3.940299	2.558212