

**School of Pharmaceutical Management****MBA Pharmaceutical Management****Batch-14th (2022-2024)****Second Year, Term 4 End Term Examination, September 2023****PHRM-731 Clinical Research and Development****Time - 3 Hour****Maximum Marks: 50 (Minimum Marks: 20)****Instructions to students:**

- This question paper contains 2 printed pages.
- Don't write anything on the Question Paper except your Enrolment No.
- F Distribution Table will be provided.

Part A**(Maximum Marks: 5)****Q1. Answer the following questions in one word:****(2 x 2.5 = 5)**

- (a). Is CDSCO approve or disapprove the drugs to be tested in Indian Population? True/False
- (b). BA/BE studies considered under Phase-III trials? True/False

Part B**(Maximum Marks: 15)****Answer the following questions, in brief.****(2 x 7.5 = 15)**

- Q2. Explain significance of Declaration of Helsinki, 1964 in clinical research.
- Q3. Describe composition, and functions of ethics committee for protocol approvals.

Part C**(Maximum Marks: 30)**

A clinical trial is run to compare weight loss programs participants are randomly assigned Program for 8 weeks. The outcome of interest is weight loss Weight measured at the start of the study (baseline) and weight measured at the end of the study (10 weeks) Weight measured in pounds.

Three popular weight loss programs are considered.

- The first is a low-calorie diet.
- The second is a low-fat diet and the third is a low carbohydrate diet.
- For comparison purposes, a fourth group is considered as a control group.
- The control group is included here to assess the placebo effect (i.e., weight loss due to simply participating in the study).

After 10 weeks, each patient's weight is again measured and the difference in weights is computed by subtracting the 10-week weight from the baseline weight as given.

N	Low Calorie	Low Fat	Low Carbohydrate	Control
1	7	1	3	2
2	8	3	4	2
3	5	2	3	-1
4	6	4	3	0
5	2	1	4	3

Apply AVOVA and answer the following questions.

Q4. Calculate the Means Squares between (MSB) the treatments and Mean Square Error (MSE). (15)

Q5. Find out a difference in mean weight loss among the four diets at $\alpha=0.05$ level of significance applying ANOVA (Refer: F-Distribution table) (15)