

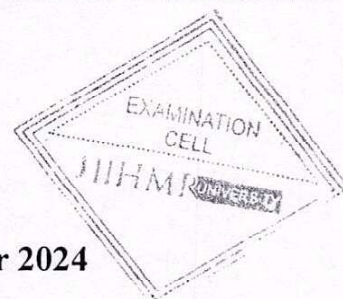


School of Pharmaceutical Management

MBA Pharmaceutical Management

Batch-15th (2023-2025)

Second Year, Term 4 End Term Examination, November 2024

**PHRM-731 Clinical Research and Development****Time - 3 Hour****Maximum Marks: 50 (Minimum Marks: 20)**

Instructions to students:

- This question paper contains 02 printed pages.
- Don't write anything on the Question Paper except writing your Enrolment No.

Part A**(Maximum Marks: 5)****Q1. State True/False for the following (1 mark each):**

- (a). CDSCO operates under the Ministry of Health and Family Welfare, Government of India.
True/False
- (b). BA/BE studies considered under Phase-III trials?
True/False
- (c). New Drugs Clinical Trial Regulations-2019, regulations provide for the approval of orphan drugs in India.
True/False
- (d). Pharmacovigilance is only applicable during the clinical trial phase of drug development.
True/False
- (e). It is ethical to withhold available treatment from control groups in clinical trials if it is for scientific purposes.
True/False

Part B**(Maximum Marks: 15)****Answer the following questions (7.5 mark each):**

- Q2. Ethics committee plays a significant role in clinical trial protocol approval justify it with its composition, and functions.
- Q3. Explain significance of Belmont Report 1949 in clinical research

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.

Apply AVOVA

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

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

(15 marks)

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 marks)

