



School of Pharmaceutical Management

Master of Business Administration

Pharmaceutical Management

Batch-10th (2018-2020) Second Year

Clinical Research and Development

Term Examination

August 2019

Time - 3 Hour

MM-70

The question paper contains 2 printed pages.

First Question is compulsory, Attempt any three from question 2-5.

Q. 1. A clinical trial is run to compare weight loss programs, participants are randomly assigned In the program for 8 weeks. Weight measured at the start of the study (baseline) and weight measured at the end of the study (8 weeks). Weight measured in pounds

After 8 weeks, each patient's weight is again measured and the difference in weights is computed by subtracting the 8-week weight from the baseline weight as given.

Test the hypothesis and find out the significance difference (at $\alpha=0.05$) in mean weight loss among four diets.

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

Answer the following questions:

- | | |
|---|----------|
| 1.1: SSB (SUM Squares between the treatments) | 10 Marks |
| 1.2. SSE (Sum squares of ERROR) | 10 Marks |
| 1.3. Construct the ANOVA table | 10 Marks |
| 1.4. Find out the F value and conclusion | 10 Marks |

Q.2. Ethics committee is essential for clinical research? How? Give its responsibilities and compositions as per ICH-GCP requirement.

10 Marks

Q.3. Describe about spontaneous reporting system in post marketing surveillance.

10 Marks

Q.4. How Pharmacovigilance is important in clinical research. Describe about the role of Pharmacovigilance Program in India (PvPi).

10 Marks

Q.5. Write short note on any two.

10 Marks

1. Essential Documentation
2. Outsourcing of clinical trials
3. Serious adverse event