M.Sc. BIOSTATISTICS EXAMS SECOND YEAR PAPER III – CLINICAL TRIAL AND ITS MANAGEMENT

Q.P. Code: 282867

Time: Three hours Maximum: 100 marks

I. Elaborate on: $(2 \times 20 = 40)$

1. Define randomised control trial and its applications.

2. What are the crossover trials and its advantages and disadvantages?

II. Write notes on: $(10 \times 6 = 60)$

- 1. Essential documents for conducting clinical trial.
- 2. Responsibilities of clinical data manager.
- 3. Clinical trial bias.
- 4. Purposes and applications of meta analysis.
- 5. Needs of randomization.
- 6. Preclinical studies.
- 7. Stopping rules for trials.
- 8. Characteristics of factorial design.
- 9. Clinical trial study.
- 10. Ethical issues for publication of data analysis.
