Seat No. : _____

TD-117

May-2013

M.Sc. (Sem.-IV)

510 : Statistics

(Bio-Statistics)

Time : 3 Hours] **[Max. Marks : 70**

Instruction : **All** questions carry equal marks.

1. (a) Define "Bio-Assay'. State objectives of Bio-Assay. Explain structure of 'Bio-Assay' in details.

OR

Discuss 'Quantal Responses' in detail.

(b) Discuss Fieller's theorem.

OR

Explain Bayesian approach to Bio-Assay.

2. (a) What is a Clinical Trial ? Explain Phase I, Phase II, Phase III, Phase IV clinical trials in detail.

OR

What are Clinical Trials needed ? Discuss various problems in the timing of a trial. What is meant by 'Ethics of Clinical Trials' ? Define 'Study Protocol'.

(b) Explain :

(i) Simple Randomization

(ii) Block Randomization

(iii) Stratified Randomization with reference to clinical trials

OR

Discuss the importance of study population in clinical trials.

3. (a) Define :

(i) Randomized control studies

(ii) Non-randomized concurrent control studies

(iii) Withdrawal studies

Explain importance of cross-over designs and factorial designs in clinical trials.

OR

Why it is important to determine sample size in clinical trials ? Discuss various methods of sample size determination.

(b) Discuss :

(i) Unblind trials

(ii) Single blind trials

(iii) Double blind trials

(iv) Triple blind trials

OR

Discuss problems in Data Collection and monitoring of drug handling. Discuss various statistical methods used in monitoring.

4. (a) What is meant by 'Survival Analysis' ? Discuss various methods used for survival analysis.

OR

What is the objective of 'Meta Analysis' ? Discuss different approaches used for Meta Analysis in clinical trials.

(b) Discuss Data Collection, Quality Control, Assessment and Reporting of Adverse Effects in clinical trials. Explain various issues in Data Analysis.

OR

Discuss in details how reporting and interpretation of results is made in clinical trials.

5. Answer the following (any **seven**) :

(a) State different types of Bio-Assays.

(b) What are PROBITS ?

(c) Explain 'End point' with a suitable example.

(d) Define Multi-Center Trials.

(e) What is the role of 'Chief Investigator' in the study of clinical trials ?

(f) Define 'Follow up' with reference to study of clinical trials.

(g) State uses of baseline data.

(h) What is 'Interim Analysis' ?