Seat No. : _____

AJ-103

April-2015

M.Sc., Sem.-IV

STA-510 (A) : Statistics

(Bio-Statistics)

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

Instructions : (1) This paper carries **70** marks.

(2) **All** questions carry equal marks.

1. (a) Define 'Biological Assays' and discuss different types of biological assays in details.

OR

Discuss various 'DOSE RESPONSE' models.

(b) Explain Bayesian approach to Bio-Assay.

OR

Discuss estimation of extreme quantiles and dose allocation schemes.

2. (a) Discuss clinical trial phases in details. Explain study protocol.

OR

Define 'Multicenter Trials'. Discuss reasons for multicenter trials and conduct of multicenter trials.

(b) Explain the terms :

(i) Randomized control studies

(ii) Non-randomized concurrent control studies

(iii) Withdrawal studies

(iv) Large simple clinical trials

OR

Discuss various methods of sample size determination in clinical trials.

3. (a) Discuss fixed allocation randomization and adaptive randomization procedures with respect to clinical trials.

OR

Explain role of cross over designs, factorial designs and group allocation designs in clinical Trials.

(b) Explain importance of 'Blindness' in clinical trials. Discuss Single blind, Double blind and Triple blind trials in details.

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

Discuss different approaches used for meta analysis in clinical trials.

(b) What is 'Interim Monitoring' ? What are the main reasons for interim monitoring ? Discuss various statistical methods used for interim monitoring.

OR

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

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

(1) Define 'Study Population'

(2) State the objective of 'Meta Analysis'

(3) What is meant by 'Relative Risk' ?

(4) State the need and ethics of clinical trials.

(5) Explain 'Somogate end points'

(6) Define 'Placebos'

(7) What is meant by 'Unblind Trials' ?

(8) Explain 'Baseline Assessment' w.r.t. clinical trials.

(9) What is 'Post Study Follow-Up' ?

(10) State objectives of 'Bio-Assay'.
