Seat No. : _____

AG-105

April-2016

M.Sc., Sem.-IV

510 A : Statistics

(Bio-Statistics)

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

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

1. (a) Define 'Bio-Assays'. Discuss various types of Bio-Assays. State objective of Bio-Assay.

OR

Discuss Fielier's Theorem and its application.

(b) Define 'Quantal Responses'. Discuss methods of estimation of parameters in brief.

OR

Define 'PROBITS'. What do you understand by Probit Analysis ? Explain the fitting of a Probit regression line through least square methods.

2. (a) Define 'Ranomized Clinical Trials'. Discuss various phases of Clinical Trials.

OR

Define 'Protocol'. Discuss Protocol Development in detail.

(b) Discuss 'Uncontrolled Trials'. State advantages and limitations of Uncontrolled Trials.

OR

Discuss 'Study Population' and 'Recruitment of Study Participant' with respect to clinical trials.

3. (a) Explain the following terms :
   (i) Simple Randomization.
   (ii) Blocked Randomization
   (iii) Stratified Randomization.
   (iv) Baseline Adaptive Randomization
   (v) Response Adaptive Randomization

OR

Discuss : (i) Unblinded Trials
(ii) Single Blinded Trials
(iii) Double Blinded Trials
(iv) Triple Blinded Trials.

(b) Discuss : (i) Cross Over Designs
(ii) Factorial Designs
(iii) Group Allocation Designs
(iv) Hybrid Designs with respect to clinical trials.

OR

What do you understand by 'Survial Analysis' ? Briefly mention the methods of estimation of Survival Probability.

4. (a) For clinical trials discuss various methods of sample size determination.

OR

Discuss Data Collection, Quality Control, Assessment and Reporting of Adverse Effects in conduct of clinical trials.

(b) What is 'Multicenter Trial' ? State reasons of conducting 'Multicenter Trials'. Explain how 'Multicenter trials' are organized.

OR

Explain issues in Data Analysis. Discuss Reporting and Interpreting of Final results.

5. Answer the brief (any **Seven**) :
(a) What is meant by 'Interim Analysis' ?
(b) Define 'PLACEBOS'.
(c) Discuss 'Ethical Issues' in conduct of clinical trials.
(d) Explain 'Relative Potency'.
(e) Define 'Surrogate Endpoints' and 'Composite Endpoints'.
(f) State uses of Baseline data.
(g) Explain the meaning of 'Poststudy Follow-up'.
(h) What is meant by 'Meta Analysis' ?
(i) Explain 'Bioequivalence Trials'.
(j) Define 'Response Variables'.

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