

[LH 0415]

OCTOBER 2015

Sub. Code: 2867

**M.Sc., NON – MEDICAL DEGREE COURSES
BRANCH II - BIOSTATISTICS
SECOND YEAR
PAPER III – CLINICAL TRIAL AND ITS MANAGEMENT**

Q.P. Code: 282867

Time: Three hours

Maximum: 100 marks

I. Elaborate on:

(2 x 20 = 40)

1. Define investigational new drug application and describes the component and categories of investigational new drug application.
2. What are the essential documents for the conducting of Clinical trials and its purpose?

II. Write notes on:

(10 x 6 = 60)

1. Various phases of clinical trial.
2. Informed consent process.
3. Central drug standard control organisation and food and drug administration.
4. Investigators brochure.
5. Randomization.
6. Source documents in clinical trial.
7. Vulnerable subjects.
8. Roles and responsibilities of regulatory authority in relation to clinical trial.
9. What are the responsibilities of clinical data manager?
10. Define the followings:
(i) Blinding (ii) Comparator (iii) Good clinical practice
