

QP Code: 106332

Reg No:

**First Year M.Pharm Degree Examinations – July 2015
(Pharmacy Practice)**

Paper II - Clinical Research and Community Pharmacy

Time: 3 hrs

Maximum Marks: 100

- *Answer all questions*
- *Draw diagrams wherever necessary*

Essays:

(2x20 =40)

1. Define the term investigational new drug application. Describe the component and categories of investigational new drug application.
2. Describe the ethical guidelines for biomedical research on human subjects.

Short Essays:

(6x10=60)

3. Discuss the role of pharmacist in family planning.
4. Explain the essential documents for conducting clinical trial and its purpose.
5. Describe the roles and responsibilities of sponsor in clinical trial as per ICH GCP.
6. Discuss in detail on drug dosing in elderly and pediatrics.
7. Describe code of ethics for community pharmacist.
8. Explain the pharmacokinetic drug interactions
