[KZ 825] **OCTOBER 2011** **Sub. Code: 3825**

DOCTOR OF PHARMACY (PHARM. D / POST BACCALAUREATE)

DEGREE EXAMINATION

FIFTH YEAR

PAPER I – CLINICAL RESEARCH

Q.P. Code: 383825

Time: Three Hours **Maximum: 100 marks**

Answer ALL questions in the same order.

I. Elaborate on :	**Pages (Max.)**	**Time (Max.)**	**Marks (Max.)**
1. a) Define investigational new drug application and describes the component and categories of investigational new drug application.	17	40 min.	20
b) What are the essential documents for the conducting of clinical trials and its purpose?			
2. a) Roles and responsibilities of auditors in clinical research			
b) Define serious adverse event in clinical trial and responsibilities of investigators in reporting	17	40 min.	20

II. Write notes on :

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