FirstRanker.com
Firstranker's choice
www.FirstRanker.com www.FirstRanker.com

[LL 825] OCTOBER 2017 **Sub. Code: 3825**

PHARM. 'D' AND PHARM. 'D' (POST BACCALAUREATE)
DEGREE EXAMINATION
(2009-2010 Regulation)
FIFTH YEAR
PAPER I – CLINICAL RESEARCH

Q.P. Code : 383825

Time : Three hours **Maximum : 70 Marks**

I. Elaborate on: **(4 x 10 = 40)**

1. Define Clinical trials. Discuss in detail about the various phases involved in Clinical trial and detail.

2. Discuss in detail about various approaches of Drug discovery.

3. Role and responsibilities of principal investigator in clinical trials.

4. Define Investigational New Drug Application (INDA) and discuss the components and categories of INDA in detail.

II. Write notes on: **(6 x 5 = 30)**

1. Post marketing surveillance.
2. Write note on Schedule – Y.
3. Safety monitoring in clinical trials.
4. Discuss in brief about different dosage forms.
5. Preparation of Informed Consent Form (ICF).
6. Role and responsibilities of data management team in clinical trials.

****

www.FirstRanker.com