Code No. 4275

FACULTY OF PHARMACY

Pharm. D (6 YDC) V-Year (Main) Examination, July 2017

Subject : Clinical Research

Time : 3 Hrs **Max. Marks: 70**

Note: Answer all questions from Part - A and answer any five questions from Part-B.

PART – A (10 x 2 = 20 Marks)

1 Mention different types of preclinical studies.
2 What are the requirements to conduct clinical trials as per schedule Y?
3 What is ANDA? How is it filed ?
4 Explain briefly the steps involved in CDM.
5 What is PIC? Explain its role.
6 What is ICMR code?
7 Define the terms “protocol” and “protocol amendments”.
8 What is a regulatory authority? Write the general roles and responsibilities of regular authority.
9 What is “subject identification code” in clinical trials?
10 Write the composition of IRB and explain quorum for meetings.

PART – B (5 x 10 = 50 Marks)

11 Explain Dosage form development process.

12 (a) Explain the principles of CDSCO GCP guidelines.
(b) Explain the roles and responsibilities of Auditors as per ICH GCP.

13 What are the contents of INDA ? How IND application is reviewed?

14 Who is a sponsor? Enumerate sponsor’s responsibilities as per ICH GCP.

15 (a) Explain randomization in clinical trials.
(b) Write notes on multicentre trials.

16 Discuss varis toxicological testing required for discovery of new drugs.

17 (a) Explain varis Data Entry methods.
(b) Write abt safety monitoring in clinical Trials.

18 (a) Explain in detail responsibilities of investigator as per ICH GCP.
(b) Give an overview of Regulatory Environment in Europe.

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