Code No. 13299

FACULTY OF PHARMACY

Pharm D (6 – YDC) V – Year (Main & Backlog) Examination, June 2019

Subject: Clinical Research

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

Note: Answer all questions from Part – A. Any Five questions from Part – B.

PART – A (10x2 = 20 Marks)

1 What is drug development? What are the steps involved in the process?

2 Write different methods of lead identification.

3 List t the key players in cl inical drug development.

4 What is NDA? How is it filed as per guidelines of schedule Y?

5 What is waiver of consent in clinical research?

6 What is IEC? Write the composition and basic responsibilities of IEC..

7 What is Regulatory Authority? Write the general roles and responsibilities of Regulatory Authority.

8 Write advantages of electronic data capture in CDM.

9 Explain the responsibilities of monitor in clinical trials.

10 What are the types of control treatments in Phase III of clinical trials?

PART – B (5x10 = 50 Marks)

11 Explain the types of preclinical studies with regulatory requirements for conduct of studies. Discuss vari8s animal pharmacology testing required for discovery of new drugs.

12 What is INDA? Explain the review process of IND application.

13 Explain varis elements of clinical trial study design.

14 Explain in detail the different methods of post marketing surveillance.

15 Give an overview of regulatory environment in Europe.

16 What is ICMR code? Explain the statement of specific principles for drug trials.

17 a) Explain varis data entry methods.

b) Write note on CRF design.

18 a) Explain varis aspects of safety monitoring in clinical trials.

b) Write note on quality assurance in CDM.

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