Code No: 1262

FACULTY OF PHARMACY

Pharm D (6–YDC) V-Year (Main & Backlog) Examination, July 2018

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 discovery? Write basic approaches to drug discovery.
2 Write note on registration of clinical trials.
3 Write different methods of lead identification.
4 List t varis functions of data management team.
5 What is periodic and interim review by EC?
6 What is waiver of consent in clinical research?
7 What is a target molecule? Write briefly the different approaches to target identification.
8 What are different control treatments in clinical trial design?
9 Explain the responsibilities of monitor in clinical trials.
10 What are “equivalence”, “superiority” and “non-inferiority” trials?

PART – B (50 Marks)

11 Explain the term “lead molecule”. Describe in detail the lead identification and optimization process.

12 List t varis responsibilities of IRB. Explain review procedures of a research proposal by IRB.

13 Explain post marketing surveillance methods.

14 Explain the components of clinical trial design.

15 Discuss varis animal pharmacology testing required for discovery of new drugs.

16 a) Give an overview of regulatory environment in USA.
b) Write detailed note on selection of special grps as research participants.

17 Explain the statement of general principles and specific principles for clinical evaluation of drugs.

18 a) Explain data capture in CDM.
b) Write note on ICF and PIC.

****