Code No. 6200 I PB

FACULTY OF PHARMACY

Pharm D (3 — YDC) II — Year (Instant) (Post Baccalaureate) Examination, January 2020

Subject: Clinical Research

Time: 3 Hours **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 What is IND "clinical hold"? Explain the basis for clinical hold.

3 List out various functions of CDSCO.

4 What is ANDA?

5 Write briefly the roles and responsibilities of CRC as per ICH GCP.

6 What is vulnerable population? How are their rights protected?

7 Enumerate the essential documents in clinical trials.

8 Write note on registration of clinical trials.

9 What is ICF?

10 What is blinding in clinical trials? What is its significance?

PART — B (5x10 = 50 Marks)

11 Explain the tools used in head identification and optimization.

12 Explain dosage form development process.

13 Explain the objectives, design and conduct of Phase 1 clinical trial studied with schedule Y requirements.

14 Explain NDA review process with contents and submission.

15 a) Explain the IEC review procedure of a research proposal.

b) Explain informed consent process.

16 Explain the role and responsibilities of sponsor in clinical trials as per ICH GCP.

17 Explain in detail the regulatory environment in USA.

18 a) Write note on clinical data storage and security.

b) Explain randomization in clinical trials.