Code No. 1125

FACULTY OF PHARMACY

Pharm. D (6 YDC) V-Year (Instant) Examination, March 2018

Subject : Clinical Research

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

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

PART – A (10 x 2 = 20 Marks)

1 What is Drug discovery? What are the steps involved in the process?
2 What is IND "clinical hold"? Explain the basis for clinical hold.
3 What is ANDA? Write note on its submission.
4 What is PMS and PSUR?
5 Write briefly the roles and responsibilities of CRC as per ICH GCP.
6 Write note on registration of clinical trials.
7 Enumerate the essential documents in clinical trials.
8 Write briefly ab t query management in CDM.
9 What is Patient information sheet?
10 What is blinding in clinical trials? What is its significance?

PART – B (5 x 10 = 50 Marks)

11 Explain the tools used in Lead identification and optimization.

12 Explain toxicity studies carried t in preclinical drug development.

13 Explain the objective, design and conduct of phase I clinical trial studies with schedule Y requirements.

14 Explain NDA review process with contents and format requirements.

15 Explain the IEC Review procedure of a research proposal.

16 Explain in detail the regulatory environment in USA.

17 (a) Explain Data Entry methods.
(b) Write abt clinical trials database lock.

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

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