

FIFTH YEAR PHARM. D : SUMMER - 2018

SUBJECT : CLINICAL RESEARCH

Day : **Thursday**
Date : **05/04/2018**

S-2018-4045

Time : **10.00 AM to 01.00 PM**
Max. Marks : **70**

N.B.:

- 1) **Q.No.1** and **Q.No.5** are **COMPULSORY**. Out of the remaining questions attempt **ANY TWO** questions from each sections.
- 2) Answers to both the sections should be written in **SEPARATE** answer books.
- 3) Figures to the right indicate **FULL** marks.

SECTION – I

- Q.1** A) Answer **ANY FOUR** of the following: [08]
i) Define IND and ANDA.
ii) What are pre-formulation studies?
iii) Explain HTS application in drug development.
iv) Drug characterization in Clinical Research.
v) Application of Bioisosters in drug design and development.
vi) Regulatory Authority of India for Clinical Research.
- B) Various approaches in drug design and development. [03]
- Q.2** Explain in detail Toxicity studies in preclinical stage. [12]
- Q.3** a) Process of filing an IND application in US. [07]
b) Target Identification and Validation. [05]
- Q.4** Write a short note on **ANY THREE** of the following: [12]
a) CDSCO guidelines for Clinical Research
b) Various methods of PMS
c) Introduction to Clinical Research
d) Lead Identification and Development

SECTION – II

- Q.5** A) Answer **ANY FOUR** of the following: [08]
i) Roles and responsibilities of a CRA in Clinical Research.
ii) Differentiate between NDA vs. ANDA
iii) PIS – ICF in Clinical Research.
iv) Composition of Ethics Committee as per Indian Guidelines.
v) What is data-lock?
vi) Define SAE.
- B) Roles and responsibilities of Auditors in Clinical Research. [03]
- Q.6** Explain Informed Consent Process in detail. [12]
- Q.7** a) Roles and responsibilities of Sponsor in clinical research. [07]
b) Roles and responsibilities of Ethics Committee in clinical research. [05]
- Q.8** Write short note on **ANY THREE** of the following: [12]
a) Data management and its components in Clinical Research
b) Safety monitoring in Clinical Research
c) Designing of CRF in Clinical Research
d) Ethical issues in implementation of guidelines

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