DOCTOR OF PHARMACY
Fifth Year Pharm. D. : SUMMER : 2022
SUBJECT: CLINICAL RESEARCH

Day : Wednesday | Time : 10:00 AM-01:00 PM
Date 04-May-2022 | **S-5749-2022** | Max. Marks: 70

N.B.:

1) **Q.N0.1** 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)** Lead Identification.
- **ii)** Pharmacological approaches in drug design in development.
- **iii)** Pre-formulation studies.
- **iv)** Lipinski's Rule of '5'.
- **v)** Guidelines in Clinical Research.
- **vi)** Define IND and ANDA.

B) High Throughput Screening in drug design and development. **[03]**

Q.2 Explain in detail various phases of Clinical Trial. **[12]**

Q.3 **a)** Introduction to Clinical Research. **[07]**
b) Ethical issues in implementation of guidelines. **[05]**

Q.4 Write a short note on **ANY THREE** of the following: **[12]**
- **a)** Overview of regulatory of Clinical Research in US
- **b)** PMS methods
- **c)** Docking in drug discovery in development
- **d)** Ethics committee in clinical Research

SECTION – II

Q.5 **A)** Answer **ANY FOUR** of the following: **[08]**
- **i)** SAE in Clinical Trials.
- **ii)** What is a CRO?
- **iii)** What is meant by Pharmacovigilance?
- **iv)** Informed Consent Process.
- **v)** ANDA application.
- **vi)** Paper CRF vs. e-CRF.

B) Principles of ICH – GCP guidelines. **[03]**

Q.6 Elaborate on data management and its components in Clinical Research. **[12]**

Q.7 **a)** Safety monitoring in Clinical Research. **[07]**
b) Protocol designing in Clinical Research. **[05]**

Q.8 Write short note on **ANY THREE** of the following: **[12]**
- **a)** NDA Application
- **b)** Designing of CRF
- **c)** Phase IV studies in Clinical Research
- **d)** Roles and responsibilities of CRC

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