Fifth Year Pharm. D : SUMMER - 2019

SUBJECT: CLINICAL RESEARCH

Day: Friday
Date: 05/04/2019

Time: 10.00 A.M. TO 01.00 P.M.
Max. Marks: 70

S-2019-4524

N.B:

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

SECTION-I

Q.1 **A)** Answer **ANY FOUR** of the following: **(08)**

i) Expand the following abbreviations ANDA and GCP.
ii) What is the need for ICH?
iii) What are the objectives of phase-II trial?
iv) What is phase '0' trial?
v) What is orange book?
vi) Define blinding in clinical trial.

B) Mention different approaches to new drug discovery. **(03)**

Q.2 Explain all the various contents of study protocol according to ICH-GCP. **(12)**

Q.3 **a)** Outline the content of IND application. **(07)**
b) Explain the process of post marketing surveillance. **(05)**

Q.4 Write short notes on **ANY THREE** of the following: **(12)**

a) EMEA
b) USFDA
c) Belmont report
d) Types of clinical trials

SECTION-II

Q.5 **A)** Answer **ANY FOUR** of the following: **(08)**

i) Define a placebo.
ii) What is Assent?
iii) Expand the following abbreviations SAE, DCGI.
iv) What is the importance of interim analysis in clinical trial?
v) What is the role of sponsor in premature termination of study?
vi) Give examples for vulnerable subjects.

B) Explain the role of monitor in the efficient conduct of clinical trial. **(03)**

Q.6 Explain the role of various documents required for the conduct of clinical trials. **(12)**

Q.7 **a)** Describe the composition and role of IRB/ IEC. **(07)**
b) Discuss in detail the responsibilities and functions of IRB/ IEC as per ICH-GCP. **(05)**

Q.8 Write short notes on **ANY THREE** of the following: **(12)**

a) Clinical data management
b) Safety reporting in clinical trials
c) Role of Biostatistics in clinical trial
d) Case report form

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