Printed Pages: 01 **Sub Code: MPL-204**

Paper Id: 298206 **Roll No.** | | | | | | | | | | |

M. PHARM.

(SEM. II) THEORY EXAMINATION 2018-19

CLINICAL RESEARCH AND PHARMACOVIGILANCE

Time: 3 Hours ***Total Marks: 70***

Note: 1. Attempt all Sections. If require any missing data; then choose suitably.

SECTION A

1. Attempt *all* questions in brief. 2 x 7 = 14

a. What is the role of GCP in clinical trials?
b. Name the authority under which Institutional Ethics Committee (IEC) is constituted.
c. What do you mean by "Run-in periods" in randomized clinical trials?
d. What is the purpose of FDA form 1572?
e. What do you mean by drug accountability records?
f. Define "Dechallenge" in Pharmacovigilance?
g. What is real-time vaccine safety surveillance?

SECTION B

2. Attempt any *three* of the following: 7 x 3 = 21

a. Discuss ICH-GCP guidelines in detail.
b. Discuss the key concepts in RCT and non-RCT designs.
c. Discuss about the preparation of clinical trial protocol of India.
d. Discuss the recent developments and future perspectives of PVPI.
e. Write a note on spontaneous reporting system.

SECTION C

3. Attempt any *one* part of the following: 7 x 1 = 7

(a) What is the role of Ethics committee in clinical trials? Write a note on amendments in Schedule Y regarding compensation.
(b) Describe objectives and organization structure of Indian council of medical research (ICMR).

4. Attempt any *one* part of the following: 7 x 1 = 7

(a) What are cohort studies? Discuss its types with advantages and disadvantages.
(b) Explain types and designs of clinical trials in detail.

5. Attempt any *one* part of the following: 7 x 1 = 7

(a) Discuss the role and importance of clinical data management.
(b) Write a note on purpose and design of Investigator's brochure.

6. Attempt any *one* part of the following: 7 x 1 = 7

(a) Discuss the role of hospitals and community pharmacists in pharmacovigilance.
(b) Describe the role of pharmaceutical industries in the improvement of pharmacovigilance sstem.

7. Attempt any *one* part of the following: 7 x 1 = 7

(a) Discuss active and passive surveillance in detail.
(b) Describe the role of pharmacoepidemiology in pharmacovigilance.

www.aktuonline.com

http://www.aktuonline.com