

**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.