Printed Pages : 1 **Roll No.** | | | | | | | | | | | **MPL-204**

M. PHARMA.

THEORY EXAMINATION (SEM–II) 2016-17

CLINICAL RESEARCH & PHARMACOVIGILANCE

Time : 3 Hours ***Max. Marks : 70***

Note : *Be precise in your answer. In case of numerical problem assume data wherever not provided.*

SECTION- A

1. Attempt all parts of this Section : **7×2=14**

(a) Write a brief note on Institutional review board.

(b) Enumerate are the various phases of clinical research.

(c) Suggest the roles and responsibilities of a sponsor in clinical research.

(d) Discuss the roles of pharmacovigilance officer in a hospital.

(e) Write a brief note on WHO International Drug Monitoring programme.

(f) What are the differences between drug toxicity and drug abuse.

(g) What are the salient features of yellow card system

SECTION- B

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

(a) Discuss in detail ICHGCP Guidelines.

(b) Write a brief note on "Contract Research Organization.

(c) Suggest the steps to be followed while preparing protocols in clinical research

(d) How will you monitor medication safety during pharmacovigilance study?

(e) How will you detect and report ADR?

SECTION- C

3. Attempt all questions in this section : **5×7=35**

(a) Discuss the ethical guidelines to be followed for biomedical research. Write a short note on ICMR.

(b) Discuss in detail the various types of observational study with special reference to case control and cross-sectional study.

OR

Write a detailed notes on Randomised Controlled trial

(c) What is investigational brochure? Describe the various stages of clinical trial monitoring.

(d) Discuss the process of establishing a pharmacovigilance centre in the hospital. Justify its significance in the current Indian context.

OR

Discuss the process of effective management of adverse drug reactions in the current context.

(e) **Write short note(any two):**

(i) Pharmaco-epidemiology

(ii) Pharmaco-economics

(iii) Vaccine safety surveillance