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

Paper Id: | 2 | 9 | 8 | 2 | 1 | 1 | **Roll No.** | | | | | | | | | | |

M. PHARM.
(SEM II) THEORY EXAMINATION 2017-18
CLINICAL RESEARCH AND PHRMACOVIGILANCE

Time: 3 Hours ***Total Marks: 75***

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

SECTION A

1. Attempt *all* questions in brief. **10 x 2 = 20**

a. Enlist ethical guidelines for biomedical research.

b. Write about importance of informed consent.

c. Define randomized clinical trial. Enlist its types.

d. Enlist the elements of case report form.

e. Write a short note on essential documents in clinical trial.

f. Write a short note on site management organization.

g. Write a short note on risk assessment.

h. Write difference between active and passive surveillance.

i. What do you mean by Aris G Pharmacovigilance System?

j. Write importance of pharmacoeconomics.

SECTION B

2. Attempt any *two* parts of the following: **2 x 10 = 20**

a. Describe structure, functions and ethical requirement of ICH-GCP.

b. Compare between WHO and Naranjo scale of causality assessment of ADRs.

c. Explain the statistical methods for evaluating medication safety data.

SECTION C

3. Attempt any *five* parts of the following: **7 x 5 = 35**

a. What are the requirements to conduct clinical trials as per schedule Y.

b. What is clinical data management? Discuss the role and importance in detail.

c. Discuss the role and responsibility of clinical research coordinators.

d. Describe the various components of a protocol?

e. Explain spontaneous reporting of adverse drug reactions with suitable examples. What are the merits and demerits of spontaneous reporting.

f. Describe the functioning of VigiFlow.

g. Discuss the origin of S7B and E14 guidelines of ICH.