Ref No. EX/PG/CLP/T/128A/2018

M.Pharm in clinical Pharmacy & Pharmacy Practice.
1st Year 2nd Semester Examination 2018.
Subject: Clinical Research-II.

Time: 3 Hrs **Full Marks: 100**

Answer any five questions

1. Define Clinical trial. What are the Objectives of Clinical trial? Mention the type of Clinical trials. Describe the different Phases of Clinical trials?

3+3+4+10=20

2. What is IEC? Write the composition of Ethics Committee. Briefly discuss the responsibilities of Ethics Committee Members.

4+6+10=20

3. Define GCP. Describe the principle of GCP. Write a short note on Investigator's Brochure.

5+5+10=20

4. Define adverse event and the term unexpectedness in context of clinical research. What is serious adverse event? Write a short note on the regulatory reporting of Serious Adverse Event in Indian context.

5+5+10=20

5. Write the significance of ICH guidelines in clinical research. Discuss the role of clinical pharmacist in the field of -- Hospital, Industrial clinical operations & Pharmacovigilance?

5+15=20

6. Answer the following
   a) Define Pharmacovigilance.
   b) Why pharmacovigilance is so important in clinical pharmacology?
   c) Define SUSAR.
   d) Write a short note on - Severity of adverse event.

4 x 5=20