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0305E344

Candidate's Seat No :_____

M.Sc. (Sem.-II) Examination

201

Clinical Research Pharma Medicine & C.R. Module-IV

May-2017

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

Que. 1 Answer any two of the following **14**

a) Write a note on QSAR

b) Explain Computer Assisted Drug Designing

c) Explain guideline about safety pharmacology studies for human pharmaceutical

d) Short Note: High Throughput Screening

Que. 2 Write a note on any two of the following **14**

a) Guideline for non clinical studies for Anticancer drugs

b) The Belmont Report

c) Clinical Trial Designs

d) The 1937 Disaster

Que. 3 Answer any two of the following **14**

a) Drug Development Process

b) Medical Writing in Clinical Trial

c) Discuss any 14 principles of Declaration of Helsinki

d) Thalidomide Tragedy

Que. 4 Write a note on any two of the following **14**

a) Site Management Organization

b) Central Laboratory

c) Preparation and Planning of a Clinical Trial

d) Draw and Discuss Organogram of a CRO

P. T.O

Module IV Pharma-Medicine & Clinical Research

14

Que. 5 Answer the following

1. What is the difference between SAR and QSAR
2. Who was the FDA inspector at the time of Thalidomide tragedy
3. Define: RMO
4. Define: Phase V Trial
5. Define: Metaanalysis
6. Which was the solvent for Sulphanilamide elixir?
7. Define: Beneficence
8. Full Form: NOAEL
9. What is the order of species used for Pharmacokinetic studies?
10. Give full form of FIH
11. Define: Pharmacoepidemiology study
12. Pre-Clinical Guideline S1A Stands for _____
13. Full form: WOCBP
14. Enlist categories of Pharmacology Studies