

MSc Sem.-2 Examination

407

Clinical Research

Time : 2-30 Hours]

May-2025

[Max. Marks : 70

Instructions:

- Question-1 to Question-4 are compulsory.
- Attempt any fourteen questions in question.5.

Que. 1 Describe the following:

- a) Explain in brief QSAR. 07
- b) Describe in detail Computer assisted drug designing. 07

OR

Que. 1 Describe the following:

- a) Write High Throughput Screening (HTS). 07
- b) Explain Confirmatory trials. 07

Que. 2 Describe the following:

- a) Discuss safety pharmacology studies for human pharmaceuticals. 07
- b) Explain in brief S4 Guidelines. 07

OR

Que. 2 Describe the following:

- a) Write ethical principles for Medical research involving human subjects. 07
- b) Write Miracle drug disaster of 1937. 07

Que. 3 Describe the following:

- a) Give an overview of nonclinical evaluation of anticancer pharmaceuticals. 07
- b) Explain in brief E4 guideline. 07

OR

Que. 3 Describe the following:

- a) Explain various types of trials. 07
- b) Explain non-clinical overview and non clinical summaries. 07

Que. 4 Describe the following:

- a) Draw flow-chart of CRO & explain any three department. 07
- b) A Note on: Site Management Organization. 07

OR

Que. 4 Describe the following

- a) Explain various fundamentals of trial design. 07
- b) Describe Clinical Trial BD operation and functions. 07

(P.T.O)

Module IV Pharma- Medicine & Clinical Research

Que. 5 Answer the following (write any 14 out of 17)

14

1. Name the culprit for Sulfanilamide Disaster.
2. Define: LAR.
3. Define : Pharmacoepidemiology
4. Define: IW.
5. Define: Single ascending dose study.
6. Enlist any 3 responsibilities of Project manager
7. Can placebo be given to control group in a trial? Yes/No. Why.
8. Define: Diagnostic trial.
9. Define: bias.
10. Prior to the first human exposure single dose toxicity should be evaluated in _____.
11. Define: Meta analysis.
12. Define Assent form.
13. IND application is required to be submitted before starting of Phase I clinical Trial.
True/False. Justify
14. In Case control study participants are directly contacted only once in the defined period.
True/False. Justify
15. Write types of blinding.
16. Define Randomization.
17. Define: power.