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1604N201A

Candidate's Seat No :_____

M.Sc Semester-2 Examination

407

Clinical Research

April-2024

Time : 2-30 Hours] **[Max. Marks : 70**

Instructions:

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

Que. 1 Describe the following:

a) Describe in detail HTS. 07

b) Write a note on Structure Activity Relationship (SAR). 07

OR

Que. 1 Describe the following:

a) Explain in brief Exploratory Trials & Confirmatory Trial. 07

b) Describe in detail Post Marketing Surveillance. 07

Que. 2 Describe the following:

a) Explain Belmont Report in detail. 07

b) Write a note on 1937 Elixir Incident. 07

OR

Que. 2 Describe the following:

a) Describe the guidelines for duration of chronic toxicity testing in animal. 07

b) Describe the guideline (M3(R1)). 07

Que. 3 Describe the following:

a) Explain in brief S9 guidelines. 07

b) Write 14 principles of WMA Declaration of Helsinki. 07

OR

Que. 3 Describe the following:

a) Describe the needs under which long term carcinogenicity studies are required for pharmaceuticals. 07

b) Describe the guideline (M4S(R2)). 07

Que. 4 Describe the following:

a) Write a work flow of Contract Research Organization. 07

b) Explain R & R of Medical Writer. 07

OR

Que. 4 Describe the following

a) Enlist differences between CRO/SMO/RMO. 07

b) Explain in various fundamentals of trial design. And explain Quality of life trial. 07

P.T.O

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Module IV Pharma- Medicine & Clinical Research

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

1. Define: Vulnerable group
2. Differentiate between Treatment Trial & Prevention Trial
3. Name the drug regulatory agency of Europe
4. Define: non- clinical trials
5. Define: Washout period.
6. CADD have more advantages over traditional drug screening. True/False. Justify
7. Define: TMO.
8. Enlist any 2 functions for Regulatory affairs.
9. Define: Factorial design.
10. What was Thalidomide prescribed for?
11. Define: Phase 0
12. Define: Sample size..
13. Define: Docking.
14. When was the last amendment done in Declaration of Helsinki.
15. _____ study design is best for drugs with long half life.
16. Phase I trials are to be conducted on animals. True/False?
17. Define: Feasibility.

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