2011E718

Candidate's Seat No :_____

M.Sc Sem-3 Examination

301

Clinical Research

November-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) Explain different Study design in BA/BE studies. 07
b) Discuss Bio statistical procedure to conduct BABE studies. 07

OR

Que. 1 Describe the following:

a) Define method of validation & discuss its parameters for generic module. 07
b) Discuss methods to document BABE according to USFDA Guidelines 07

Que. 2 Describe the following:

a) Guidelines for report preparation according to ANVISA Guidelines. 07
b) Explain reference and test product selection in a BABE study according to EMEA Guidelines. 07

OR

Que. 2 Describe the following:

a) Directorate General of Foreign Trade 07
b) General Considerations for BABE Study according to Brazilian Guideline 07

Que. 3 Describe the following:

a) Discuss the similarities and differences in bioequivalence guidelines on Following parameters 07
   - Requirement of Fed study & Retention quantities of study drugs
b) Differences in BE guideline with reference to inclusion and exclusion criteria 07

OR

Que. 3 Describe the following:

a) Enlist different global regulatory & their role in bioavailability studies. 07
b) Differences in BE guidelines with reference to 07
   - Selection of test and reference products & Drug content and potency.

Que. 4 Describe the following:

a) Explain the study workflow in a BABE unit. 07
b) Write a note on BABE study budget. 07

OR

Que. 4 Describe the following

a) Write roles and responsibilities of PM and BD Departments. 07
b) Explain R&R of Quality Assurance and Quality control in BABE studies. 07

(P.T.O)

E718-2

Module VII CONDUCT OF BIOEQUIVALENCE STUDIES

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

1. Define: Cross Validation
2. Write full form of PBD_____
3. Define : Sensitivity
4. Briefly explain packaging details of study product as per EMEA Guidelines
5. Write minimum sampling time points required for BE study
6. Define: Generic Drug
7. If an amendment is necessary to eliminate an apparent immediate hazard to the safety of subjects in a trial, it should:
   a) Be implemented before IRB review
   b) Be implemented immediately after IRB review
   c) Be handled by expedited review
   d) Be reported to the regulatory before going to the IRB.
8. Define: Evidence-based Medicine
9. Smokers are not eligible to participate in Clinical Trial. True/False Justify
10. Write down two responsibilities of a medical writer
11. Define: Comparative Clinical Trial
12. Define: Biowaiver
13. Write down the number of subjects required for BE study (pilot and pivotal)
14. Enlist any 5 responsibilities of Corporate Communication Department
15. Explain Washout
16. Define: non-liner pharmacokinetics.
17. Describe requirement of fed study.