

Reg.No.:



VIVEKANANDHA COLLEGE OF ENGINEERING FOR WOMEN
[AUTONOMOUS INSTITUTION AFFILIATED TO ANNA UNIVERSITY, CHENNAI]
Elayampalayam – 637 205, Tiruchengode, Namakkal Dt., Tamil Nadu.

Question Paper Code: 90033

M.E. / M.Tech. DEGREE END-SEMESTER EXAMINATIONS – FEB. 2025

First Semester

Biotechnology

P23BT101 – CLINICAL TRIAL MANAGEMENT

(Regulation 2023)

Time: Three Hours

Maximum: 100 Marks

Answer ALL the questions

Knowledge Levels (KL)	K1 – Remembering	K3 – Applying	K5 - Evaluating
	K2 – Understanding	K4 – Analyzing	K6 - Creating

PART – A

(10 x 2 = 20 Marks)

Q.No.	Questions	Marks	KL	CO
1.	Define Inclusion and Exclusion criteria.	2	K2	CO1
2.	Illustrate two reasons for termination of clinical trials.	2	K2	CO1
3.	Explain Informed Consent.	2	K2	CO2
4.	Compare Beneficence and Non-Maleficence.	2	K2	CO2
5.	Outline difference between ANDA and NDA.	2	K2	CO3
6.	Explain Health Insurance Portability & Accountability Act.	2	K2	CO3
7.	Interpret audit in Clinical trial management.	2	K3	CO4
8.	Define Pharmacovigilance.	2	K4	CO4
9.	State the concept of pharmacoepidemiology.	2	K4	CO5
10.	Define BE & BA studies.	2	K3	CO5

PART – B

(5 x 13 = 65 Marks)

Q.No.	Questions	Marks	KL	CO
11.	a) Outline detailed note on Clinical trials in India.	13	K2	CO1
	(OR)			
	b) Write a detailed note on randomization and its methods.	13	K2	CO1
12.	a) Define historical guidelines in Clinical Research.	13	K3	CO2
	(OR)			
	b) Discuss in detail the ethics involved in animal studies.	13	K3	CO2
13.	a) Summarize different types of FDA inspections.	13	K2	CO3
	(OR)			
	b) Elaborate on Patent laws & regulations.	8+5	K2	CO3
14.	a) Write a detailed note on Clinical trials management.	13	K4	CO4
	(OR)			
	b) Explain in detail the essential documents required for conducting clinical trials.	13	K4	CO4
15.	a) Discuss the tools used in clinical data management (CDM).	13	K3	CO5
	(OR)			
	b) Extend a detailed note on discrepancy in clinical data management with few examples.	13	K3	CO3

PART – C

(1 x 15 = 15 Marks)

Q.No.	Questions	Marks	KL	CO
16.	a) Elaborate in detail about the various phases involved in drug discovery and development.	15	K2	CO1
	(OR)			
	b) Discuss about the ICMR guidelines for Biomedical Research on human subjects.	15	K3	CO5