Name:

Enrolment No:

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES

End Semester Examination, December 2022

Course: Global regulations of clinical trial **Semester : 3rd**

Program: B.Sc (Clinical Research) **Duration : 3 Hours**

Course Code: HSCR2008 **Max. Marks: 100**

Instructions: Attempt all

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	Cos
Q 1	Three unifying ethical principles of Belmont report were ____, ____, &___.	1.5	CO1
Q 2	1st conference of ICH happened in ____.	1.5	CO1
Q 3	Name three founding members of ICH.	1.5	CO1
Q 4	State three responsibilities of non-voting members of ICH.	1.5	CO1
Q 5	What ethical violation took place in Tuskegee syphilis study?	1.5	CO1
Q 6	What is the ethical basis of GCP?	1.5	CO1
Q 7	Mention any four medical devices regulated by CDSCO.	1.5	CO2
Q 8	Describe advantages of NDA505(b)(2) over NDA505(b)(1).	1.5	CO2
Q 9	Explain “placebo controlled” clinical trials.	1.5	CO2
Q 10	Describe DMF and CFR.	1.5	CO2
Q 11	Explain confirmatory trials.	1.5	CO2
Q 12	Explain “principle of essentiality”.	1.5	CO2
Q 13	What can a PI do if he does not agree that post market surveillance is appropriate.	1.5	CO3
Q 14	Explain general plan guidance in relation to post market surveillance?	1.5	CO3
Q 15	Which of the following is an International regulatory authority for drug regulation a. CDSCO b. US-FDA c. WHO d. EMA	1.5	CO3
Q 16	When and where is post market surveillance plan submitted?	1.5	CO3
Q 17	Differentiate Post market surveillance and Prospective surveillance.	1.5	CO4
Q 18	Elaborate the objective of ISO 14155.	1.5	CO4
Q 19	The objective of FDA- India office is- a. To ensure the safety, quality, and effectiveness of medical products and food produced in India for export to the United States. b. Approval of medical products for marketing in India	1.5	CO4

	c. Import of drug in India for test and examination d. Manufacture of drugs in USA for the purpose of export to India		
Q 20	How can critical quality factors identified?	1.5	CO4
Section B (4Qx5M=20 Marks)			
Q 1	State the qualification and responsibilities of clinical trial investigator.	5	CO1
Q 2	Describe registration process of medical devices in India.	5	CO2
Q 3	Write a note on “Bioavailability and Bioequivalence requirements".	5	CO3
Q 4	Illustrate with special reference to “pharmacodynamic” and “pharmacokinetics”, the need for special guidelines for geriatric patients.	5	CO4
Section C (2Qx15M=30 Marks)			
Q 1	When can a sponsor/PI charge IND application? Elaborate on essential content of IND.	15	CO3
Q 2	Demonstrate the scope of statistical principles guidelines for clinical trials. Mention in detail steps to be taken to avoid bias in clinical trials.	15	CO4
Section D (2Qx10M=20 Marks)			
Q 1	Define ICH and explain its purpose. Explain the steps of guideline approval process in ICH.	10	CO1
Q 2	Describe the application approval procedure for generic products.	10	CO2