Name:

Enrolment No:

UPES

End Semester Examination, May 2024

Course: Global Regulations of Clinical Trials | **Semester: IV**
Program: Int. (B. Sc. + M. Sc. (Clinical Research)) | **Duration: 3 Hours**
Course Code: HSCR2021 | **Max. Marks: 100**

Instructions: Attempt all sections.

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q 1	State the name of guidelines that discuss the provisions for NDA applications.	1.5	CO1
Q 2	Enumerate the purpose of ICH E11 guidelines.	1.5	CO1
Q 3	Mention the duties of IRB.	1.5	CO1
Q 4	As per schedule Y, appendix ____ focuses on reporting adverse events in clinical trials. A. VIII B. IX C. XI D. X	1.5	CO2
Q 5	State the name of the ICH of E10 guidelines.	1.5	CO1
Q 6	Mention any three examples of special population that is considered for clinical trials.	1.5	CO1
Q 7	Explain the purpose of Rule 122 D of schedule Y.	1.5	CO1
Q 8	Use of just a single dose has been typical of large-scale intervention studies (e.g., post-myocardial infarction studies) because of the large sample sizes needed. A. True B. False	1.5	CO2
Q 9	The term that explains the rate and extent of the drug reaching to systemic circulation is known as _____ of the dosage forms.	1.5	CO3
Q 10	Exclusivity of the patent is _____year exclusivity for new clinical investigations.	1.5	CO1
Q 11	In case of renal failure, sometimes the younger patients are never involved in clinical studies for comparison with geriatric population. A. True B. False	1.5	CO2
Q 12	For any application submitted for a covered product, an applicant shall retain records as described in paragraph (a) of this section for _____ years after the date of approval of the application. (21 CFR Part 54) A. 2 B. 1	1.5	CO1

	C. 4 D. 3		
Q 13	Define bioavailability.	**1.5**	**CO1**
Q 14	Name the CFR 21 Part 54 guidelines.	**1.5**	**CO1**
Q 15	The protection of human rights is explained by 21 CFR Part ___. A. 54 B. 50 C. 312 D. 314	**1.5**	**CO1**
Q 16	Differentiate between INDA and ANDA.	**1.5**	**CO3**
Q 17	Predict the application of CFR 21, PART 50 guidelines	**1.5**	**CO4**
Q 18	NDA applications are approved by _____. A. Food and Drug Administration B. Institutional review board C. Institutional ethics committee D. Animal ethics committee	**1.5**	**CO1**
Q 19	Enlist the applications of schedule Y, Drugs and Cosmetics Act 1940.	**1.5**	**CO4**
Q 20	ANDAs are submitted under section 505(b)(1) and approved under section _____. B. 505(a) B. 505(c) C. 505(j) D. 505(i)	**1.5**	**CO4**
Section B (4Qx5M=20 Marks)			
Q 1	Explain the different control groups used in clinical trials.	**5**	**CO2**
Q 2	Discuss the exception from informed consent requirements for emergency research.	**5**	**CO2**
Q 3	Describe the optional titration design for clinical trials.	**5**	**CO2**
Q 4	Enlist the types of evidence to establish the bioequivalence and comment on timelines for retention of bioequivalence samples.	**5**	**CO2**
Section C (2Qx15M=30 Marks)			
Q 1	Detail the requirements for filing IND and phases of investigation pertaining to IND.	**15**	**CO4**
Q 2	Discuss the components and draft a dummy informed consent form for conducting a clinical trial.	**15**	**CO4**
Section D (2Qx10M=20 Marks)			
Q 1	Discuss the pharmacodynamics dose response studies and drug-drug interactions, as per ICH E7 guidelines for geriatrics.	**10**	**CO3**
Q 2	Describe the general principles of clinical studies.	**10**	**CO3**