Name: Enrolment No:	

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES
End Semester Examination, May 2023

Course: Global Regulations of Clinical Trials **Semester : IV**
Program: Integrated B.Sc.+M.Sc. (Clinical Research) **Time : 03 hrs.**
Course Code: HSCR2021 **Max. Marks: 100**

Instructions:

SECTION A

S. No.	MCQs or Fill in the blanks (1.5 marks each)	30 Marks	CO
1	What are the types of IND?	1.5	CO1
2	Define new drug as per schedule Y of Drugs and Cosmetics Act.	1.5	CO1
3	Clinical trials and import of the new drug is regulated as per the schedule Y of Drugs and Cosmetics act. A. True B. False	1.5	CO1
4	What is the purpose of ICH E7 guidelines?	1.5	CO1
5	Which of the following populations are considered as special populations? (Select all possible answers. A. Geriatric B. Pregnant women C. Pediatric D. Cancer patients	1.5	CO2
6	As per 21 CFR-part 50 exceptions from general requirement for informed consent is given under_____ . A. 50.20 B. 50.23 C. 50.24 D. 50.25	1.5	CO1
7	In parallel design of clinical trials____. A. Same doses are administered to same sample population multiple times. B. Same doses are administered to same sample population C. Different doses are administered to same sample population D. Different doses are administered to different sample population same time	1.5	CO3
8	What are the disadvantages of cross-over design?	1.5	CO1
9	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	CO1
10	What is the placebo dosage form?	1.5	CO2
11	Which of the following is not covered under ICH E8 guidelines? A. Protection of clinical study participants B. Scientific approach in clinical study design, planning, conduct, analysis, and reporting C. Import of new drug	1.5	CO2

	D. Quality by design of clinical studies		
12	Differentiate commercial and non-commercial INDA.	**1.5**	**CO3**
13	In manufacturing information of INDA, which of the following is not necessary?? A. Composition B. Manufacturer details C. Pre-clinical data D. Stability data	**1.5**	**CO1**
14	What is CDER?	**1.5**	**CO1**
15	In which book all the approved drugs are listed? A. Black book B. Orange book C. Red book D. Silver book	**1.5**	**CO1**
16	Define active ingredient.	**1.5**	**CO1**
17	Within ____ days after FDA receives an NDA, the Agency will determine whether the NDA may be filed or not. A. 180 B. 60 C. 30 D. 365	**1.5**	**CO1**
18	What are some examples of 505(b)(2) applications? (any three)	**1.5**	**CO3**
19	What is NDA?	**1.5**	**CO1**
20	The drug for which patent is already expired, in the case ANADA ia filed under paragraph IV. A. True B. False	**1.5**	**CO4**
	SECTION B		
Q	Short Answer Type Question	**20 Marks**	**CO**
1	Summarize the importance of IND.	**5**	**CO2**
2	How the disputes in NDA approval process are resolved?	**5**	**CO2**
3	Describe paragraph I to IV with respect to ANDA application.	**5**	**CO2**
4	What kind of application can be submitted as a 505(b)(2) application?	**5**	**CO2**
	SECTION C 30 marks		
Q	**Two case studies 15 marks each subsection**	**30 Marks**	**CO**
1	Summarize and design a flowchart for the complete review process on investigational new drug application process.	**10+5**	**CO4**
2	Discuss in detail the informed consent form in clinical trials.	**15**	**CO3**
	SECTION- D 20 marks		
Q	Long Answer type Questions	**20 Marks**	**CO**
1	Discuss the following with respect to Studies in Support of Special Populations: Geriatrics. a. Pharmacokinetics in renally or hepatically impaired patients b. Pharmacodynamics Dose Response Studies	**5+5**	**CO3**
2	Co-relate the drug concentration-response data to its use in clinical trials.	**10**	**CO3**