Name: Enrolment No:	UPES UNIVERSITY WITH A PURPOSE

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES
Online End Semester Examination, January 2021

Course: Guidelines, Regulations and Ethics in Clinical Trials **Semester: VIII**
Program: Clinical research **Time 03 hrs.**
Course Code: **Max. Marks: 100**

SECTION A

1. **Each Question will carry 5 Marks**
2. **Instruction: Complete the statement / Select the correct answer(s)**

S. No.	**Question**	**CO**
Q 1	Expand the terms a. ANDA b. IND c. ICH d. CDSCO e. GCP	**CO1**
Q2	a. ICH E6 guidelines is related to _____ b. What do you mean by post marketing surveillance c. Another word for dummy medicine is _____ d. Phocomelia is associated with which drug _____ e. Tuskegee study is related to which disease ?	**CO1**
Q3	Match the following a. E7 – p. Dose Response Information to support Drug Registration b. E4 – q. Studies in support of General Population: Geriatrics c. E8 – r. General Considerations of Clinical Trials d. E10 – s. Choice of Control Groups and Related Issues in Clinical Trials, e. E 11 – t. Clinical Investigation of Medicinal Products in the Paediatric Population	**CO4**
Q4	Why is dose response information important. (1 mark) Write about information written in Investigational New Drug application. (4 marks)	**CO3**
Q5	Define terms a. Bioavailability b. Bioequivalence Also give the range for bioequivalence.	**CO4**

Q6	Write about market exclusivity for New chemical entity, new chemical entity for organ disease, first to file ANDA and for NDA 505(b)	**CO3**
SECTION B **1. Each question will carry 10 marks** **2. Instruction: Write short / brief notes**		
Q 1	Mention any 4 different types of control groups. Explain any two of them.	**CO3**
Q 2	Discuss important points mentioned in Belmonts report regarding ethics in clinical research.	**CO5**
Q 3	Write about vulnerable population. Why is the name vulnerable used for them. a. In which phase of clinical trials are geriatric population enrolled. Give all possible cases.	**CO1**
Q 4	Write some principles of Good Clinical Practices. (At least 6)	**CO4**
Q 5	Write about special treatment given (or should be given) to a. Pregnant women b. Pediatrics	**CO5**
Section C **1. Each Question carries 20 Marks.** **2. Instruction: Write long answer.**		
Q1	Write about a. ANDA b. NDA 505(b) c. IND d. Orange book OR a. Write about life span of a drug including patent protection and market exclusivity given by FDA. b. Mention salient feature of Hatch Waxman Act and the benefits it has for generic and branded products	**CO2**