


Name:		 UPES UNIVERSITY WITH A PURPOSE
Enrolment No:		
UNIVERSITY OF PETROLEUM AND ENERGY STUDIES Online End Semester Examination, January 2021		
Course: Guidelines, Regulations and Ethics in Clinical Trials Program: Clinical research Course Code:		Semester: VIII Time 03 hrs. 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 <p style="text-align: center;">OR</p> 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