Name: Enrolment No:	UPES UNIVERSITY WITH A PURPOSE

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES
End Semester Examination, December 2021

Course: Drug Regulation and Registration **Semester: III**
Program: Clinical research **Time 03 hrs.**
Course Code: HSCR 8007P **Max. Marks: 100**

SECTION A

Each Question will carry 1.5 Marks

S. No.	**Question**	**CO**
Q 1	Which schedule defines shelf life of drugs	**CO2**
Q 2	Define abbreviated new drug application	**CO1**
Q 3	Give full form of CDSCO	**CO2**
Q 4	Schedule H describes _____	**CO1**
Q 5	What is the significance of Drug and Price Control Order	**CO1**
Q 6	Name the present Drug Controller General of India	**CO4**
Q 7	In which year Hatch Waxman act was first enacted.	**CO4**
Q 8	Define pharmacovigilance	**CO2**
Q 9	What is the maximum period of extention given to NCE under Hatch Waxman Act	**CO2**
Q 10	What do you mean by orange book	**CO4**
Q11	What are non-prescription drugs	**CO3**
Q 12	Give two examples of non-prescription drugs	**CO3**
Q 13	Regulations and standards for vaccines are mentioned in schedule _____	**CO3**
Q 14	What are essential drugs	**CO4**
Q 15	Medical Devices are included in the new definition of drugs. True /False	**CO1**
Q 16	Define term orphan drugs	**CO4**
Q 17	Name the regulatory authority of India	**CO3**

Q18	Name the regulatory authority for Australia	**CO2**
Q 19	Homeopathic, Ayurvedic and Unani medicines are covered under drugs and cosmetics act. True/False	**CO3**
Q 20	Which schedules describes Cosmetics products	**CO3**
SECTION B **1. Each question will carry 5 marks (not more than 150 words)** **2. Instruction: Write short / brief notes**		
Q 1	What do you mean by Abbreviated New Drug Application (ANDA). How it is different from NDA 505(b).	**CO1**
Q 2	What is drug price control order (DPCO) and why is it required. Give examples of drugs under this order.	**CO2**
Q 3	Write Salient features of Drugs and Magic remedies act 1954, India.	**CO4**
Q 4	Write about market exclusivity for a. New chemical entity b. New chemical entity for orphan disease c. First to file ANDA d. For NDA 505(b) e. Second to file ANDA	**CO3**
Section C **1. Each Question carries 15 Marks.** **2. Instruction: Write long answer.**		
Q 1	Write about the salient features of New Drugs and Clinical Trials Rules 2019. (at least 8 points)	**CO3**
Q 2	Write about the role of following regulatory agencies/bodies of India a. DTAB b. CDSCO e. IRB/IEC	**CO1**
Section D **3. Each Question carries 10 Marks** **4. Instruction: Write long answer. (300 words)**		
Q 1	Give essential features of Hatch Waxman act.	**CO4**
Q 2	Write about some salient features of Drugs and Cosmetics act covering different types licensing, different types of medicines and manufacturing conditions.	**CO2**