Name:

Enrolment No:

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES
End Semester Examination, December 2022

Course: Drug Regulation and Registration **Semester: III**
Program: MSc Clinical Research **Duration: 3 Hours**
Course Code: HSCR8007 **Max. Marks: 100**

S. No.	Section A Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)	Marks	COs
Q 1	…….. are the committees related to EU Regulations a. TGA b. CDER c. CBER d. COMP	**1.5**	**CO1**
Q2	What is BLA?	**1.5**	**CO4**
Q3	If a drug is colored or coated to conceal the damage in it, under which category of drugs shall it come? a) Misbranded drugs b) Spurious drugs c) Adulterated drugs d) Impure Drugs	**1.5**	**CO3**
Q4	What is “IND” and “ANDA”?	**1.5**	**CO2**
Q5	What is “Post marketing surveillance”?	**1.5**	**CO3**
Q6	Schedule ……..of the D&C Act 1940 and Rules 1945 deals with the guidelines for Good Clinical Practices a. Y b. M c. P d. X	**1.5**	**CO3**
Q7	Animal studies, clinical trials, bioavailability studies are part of which application process a. IND b. NDA c. ANDA d. BLA	**1.5**	**CO3**
Q8	If the container of the drug has any poisonous and deleterious substances, which type of drug this will be? a) Misbranded drugs b) Spurious drugs	**1.5**	**CO2**

	c) Adulterated drugs d) Impure Drugs		
Q9	CFR stands for a. Code of Federal Regulations b. Centre of Federal Regulations c. Code of Federal Register d. Centre of Federal Regulator	**1.5**	**CO1**
Q10	If any organization wishes to market their product only in one EU country, then_____ is preferred procedure. a. National Procedures b. Mutual recognition Procedure c. Centralized Procedure d. decentralized Procedure	**1.5**	**CO4**
Q11	Marketing Authorization Application (MAA) is an application to the relevant authority to market a drug or medicine in a. US market b. Europe market c. Canadian market d. All countries	**1.5**	**CO2**
Q12	The objective of FDA- India office is …... a. To ensure the safety, quality, and effectiveness of medical products and food produced in India for export to the United States. b. Approval of medical products for marketing in India c. Import of drug in India for test and examination d. Manufacture of drugs in USA for the purpose of export to India	**1.5**	**CO3**
Q13	Indian Pharmacopoeia Commission headquarter is located at a. Delhi b. Mumbai c. Hyderabad d. Ghaziabad	**1.5**	**CO3**
Q14	Which book contains list of approved drugs and their IPR?	**1.5**	**CO1**
Q15	Define “Spurious drugs”.	**1.5**	**CO2**
Q16	Define “SUPAC”	**1.5**	**CO2**
Q17	What is Orphan drug? Give one example.	**1.5**	**CO2**
Q18	Give three examples of OTC drugs.	**1.5**	**CO2**
Q19	Define “Trademark”.	**1.5**	**CO1**
Q20	What is “Drug Master File”?	**1.5**	**CO2**
Section B (4Qx5M=20 Marks)			
Q 1	Discuss Post Marketing Surveillance.	**5**	**CO4**

Q 2	Explain WHO certification scheme on the quality of pharmaceutical products moving in international commerce.	**5**	**CO3**
Q 3	Discuss the history of drug regulation in USA.	**5**	**CO2**
Q 4	Mention the general penalties as applicable to drugs, cosmetics and biotechnological Products	**5**	**CO1**
Section C **(2Qx15M=30 Marks)**			
Q 1	a) Discuss Indian Patents and Designs, Act 1970, including recent amendments. b) Explain Indian laws on Trademarks and Copy Rights.	**15** **(8+7 marks)**	**CO4**
Q2	a) Differentiate USFDA and EU regulation guidelines for Drug Registration process. b) Explain in detail about drug registration process in India.	**15** **(10+5 marks)**	**CO3**
Section D **(2Qx10M=20 Marks)**			
Q 1	Describe regulatory considerations for manufacturing, packaging and labeling of pharmaceuticals in EU.	**10**	**CO1**
Q2	Discuss the organization and functions of FDA, including historical developments.	**10**	**CO2**