Name:

Enrolment No:

UPES

End Semester Examination, May 2024

Course: Pharmaceutical Regulatory Science **Semester : VIII**

Program: B. Pharma **Duration : 03 Hours**

Course Code: BP 804ET **Max. Marks: 75**

Instructions: Attempt all questions. All questions are compulsory

SECTION A

(20Qx1M=20 Marks)

S. No.		Marks	COs
Q 1	Define NDA.	**1**	CO1
Q 2	Define ANDA.	**1**	CO1
Q 3	Define clinical trial.	**1**	CO1
Q 4	Importance of DMF.	**1**	CO1
Q 5	The number of members in IRB board are a. 1 b. 2 c. 8 d. 5	**1**	CO2
Q 6	No of sections in ACTD are a. 1 b. 2 c. 4 d. 3	**1**	CO2
Q 7	Which of the following DMF is discontinued? a. Type I b. Type II c. Type III d. Type IV	**1**	CO2
Q 8	Define Pharmacovigilance.	**1**	CO2
Q 9	Subjects should be informed that they may decline to take part in the clinical investigation or may stop participation at any time without penalty or loss of benefits to which subjects are entitled. (True/False)	**1**	CO3
Q 10	Which module is not a part of CTD? a. Module I b. Module II c. Module III d. Module IV	**1**	CO3
Q 11	Labels on packages or containers of drugs for export shall be adapted to meet the specific requirements of the law of the Country, to which the drug is to be exported. (True/False)	**1**	CO3
Q 12	COPP is required for export of drug from India. (True/False)	**1**	CO3

Q 13	Module 2 is not present in ACTD Document. (True/False)	**1**	CO4
Q 14	Module 4 of CTD consists of a. Non-Clinical Study reports b. Clinical Study report c. Quality d. Summary of all of the above	**1**	CO4
Q 15	Book containing a list of generic drugs is known as _____	**1**	CO4
Q 16	Give the name of regulatory body of Australia.	**1**	CO4
Q 17	Give full form of CDSCO.	**1**	CO5
Q 18	Give name of Regulatory bodies of US.	**1**	CO5
Q 19	BLA is filed for approval of biological products.(True/False)	**1**	CO5
Q 20	IND is submitted to regulatory bodies for permission to conduct clinical trials. (True/False)	**1**	CO5
SECTION B (20 Marks) **(2Qx10M=20 Marks)**			
Q 1	Discuss the various modules and requirements of Common Technical Document (CTD) and compare it with ASEAN common technical documents(ACTD).	**10**	CO3
Q2.	Discuss in details the various stages of development of new drugs.	**10**	CO4
Q3.	Discuss in detail about a. Institutional Review Board b. Informed consent process and procedures	**5x2=10**	CO5
SECTION-C (35 Marks) **(7Qx5M=35 Marks)**			
Q 1	Explain safety monitoring with special reference to pharmacovigilance.	**5**	CO1
Q 2	Discuss the importance of pharmaceutical regulatory affairs in industry.	**5**	CO1
Q 3	Write a note on Exclusivities given by USFDA for drugs.	**5**	CO1
Q 4	Write a note on organization and function of USFDA.	**5**	CO2
Q 5	Write a note on NDA submitted to regulatory bodies.	**5**	CO2
Q 6	Write a note on orange book.	**5**	CO3
Q 7	Discuss GCP obligations of Investigators.	**5**	CO3
Q 8	Write a note on Changes to an approved NDA / ANDA.	**5**	CO4
Q 9	Discuss about a. Innovator and generic drugs. b. Health Canada.	**5**	CO5