Name: Enrolment No:	

UPES

End Semester Examination, May 2025

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	Orange book contains a list of approved drugs and their associated IPR. a) True b) False	**1**	CO1
Q 2	Common Technical Document (CTD) is divided into _____modules. a) 2 b) 3 c) 5 d) 7	**1**	CO1
Q 3	Which of the following is an International regulatory authority for drug regulation? a) CDSCO b) WHO c) UNESCO d) EMA	**1**	CO1
Q 4	Which of the following is drug regulatory authority of the UK? a) Pharmaceutical and Medical Devices Agency (PMDA) b) Medicines and Healthcare products Regulatory Agency (MHRA) c) Central Drug Standard Control Organization (CDSCO) d) Therapeutic Goods Administration (TGA)	**1**	CO1
Q 5	What is the primary purpose of drug regulations? a) To control drug pricing b) To ensure the safety, efficacy, and quality of drugs c) To promote pharmaceutical companies d) To limit the availability of new drugs	**1**	CO1
Q 6	What does ANDA stand for in drug development? a) Application for New Drug Approval b) Approved New Drug Application c) Abbreviated New Drug Approval d) Abbreviated New Drug Application	**1**	CO2
Q 7	Which of the following is NOT associated with Phase 1 clinical trials? a) ~ 100 participants incorrect b) Patients with target disease correct c) Establishment of safety of drug in humans incorrect d) Establishment of normal human dosage incorrect	**1**	CO2
Q 8	In pharmacovigilance, the term ADR stands for _ a) Adverse Drug Reaction b) Adverse Dose Reaction	**1**	CO2

	c) Absolute Drug Reaction d) Absolute Dose Reaction		
Q 9	CFR stands for: a) Code of Federal Regulations b) Centre of Federal Regulations c) Code of Federal Register d) None of the above	**1**	CO3
Q 10	What is the major difference between an NDA and an ANDA? a) NDA requires clinical trials, while ANDA does not b) NDA is for generic drugs, while ANDA is for innovator drugs c) NDA is approved by EMA, while ANDA is approved by FDA d) NDA requires a shorter approval timeline compared to ANDA	**1**	CO3
Q 11	Which of the following is regulatory authority of Australia? a) Pharmaceutical and Medical Devices Agency b) Therapeutic Goods Administration c) Medicines and Healthcare Products Regulatory Agency d) Central Drug Standard Control Organization	**1**	CO3
Q 12	What is the purpose of the Drug Master File (DMF)? a) To provide detailed information about a drug's formulation and manufacturing process b) To submit preclinical animal study data c) To replace the need for an NDA submission d) To conduct bioequivalence studies	**1**	CO3
Q 13	Which module of the CTD contains administrative and regional information? a) Module 1 b) Module 2 c) Module 3 d) Module 4	**1**	CO4
Q 14	Module 3 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	Which Schedule of the D&C Act 1940 and Rules 1945 deals with the guidelines for Good Clinical Practices? a) Schedule Y b) Schedule M c) Schedule P d) Schedule X	**1**	CO4
Q 16	Below is a searchable, online database that contains information about biological products, including biosimilar and interchangeable biological products, licensed (approved) by the FDA under the Public Health Service Act. a) Orange Book b) Purple Book c) Federal Register d) Drug Master File	**1**	CO4

Q 17	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**	CO5
Q 18	What does Informed Consent in clinical trials ensure? a) That participants are forced to take the treatment b) That participants understand the risks, benefits, and procedures c) That the investigator is not responsible for adverse events d) That the study is anonymous	**1**	CO5
Q 19	To begin clinical research study, it is mandatory to get approval from: a) Sponsor b) Investigator c) Regulator d) Regulators and ethics committee both	**1**	CO5
Q 20	What is the main objective of preclinical studies? a) To test drug safety and efficacy in humans b) To assess pharmacokinetics and toxicity in animals c) To obtain regulatory approval d) To manufacture drugs for commercial use	**1**	CO5
SECTION B (20 Marks) (2Qx10M=20 Marks)			
Q 1	Discuss the development of clinical trial protocols in detail.	**10**	CO3
Q 2	Describe how the Common Technical Document (CTD) and electronic Common Technical Document (eCTD) help in global drug registration.	**10**	CO4
Q 3	Define generic drugs. What are the regulatory requirements for developing a generic drug product? (Mention bioequivalence studies, ANDA submission, *etc*.).	**10**	CO5
SECTION-C (35 Marks) (7Qx5M=35 Marks)			
Q 1	Compare and contrast NDA and ANDA submissions in terms of data requirements and regulatory pathways.	**5**	CO1
Q 2	Explain the informed consent process and procedure involved in clinical trials.	**5**	CO1
Q 3	Explain the export process of pharmaceutical products from India.	**5**	CO1
Q 4	Explain the purpose of an Institutional Review Board. Describe its formation and working procedures.	**5**	CO2
Q 5	Explain the purpose and procedures of pharmacovigilance in the context of clinical trials.	**5**	CO2
Q 6	Explain the Orange Book features.	**5**	CO3
Q 7	Explain various phases of clinical trials.	**5**	CO3
Q 8	Describe the organizational structure and roles of the Central Drugs Standard Control Organization (CDSCO).	**5**	CO4
Q 9	Define Drug Master File (DMF). Discuss its significance in pharmaceutical product development.	**5**	CO5