Graphic Era HILL UNIVERSITY
Established by an Act of the State Legislature of Uttarakhand (Adhiniyam Sankhya 12 of 2011)
University under section 2(f) of UGC Act, 1956

End Term (Even) Semester Examination May-June 2025

Roll no.....

Name of the Program and semester: B. Pharm.
Name of the Course: Pharmaceutical Regulatory Science
Course Code: BP804ET
Time: 3 hours

Maximum Marks: 75

Note:
(i) This question paper contains three sections
(ii) All the sections are compulsory
(iii) All questions should cover COs of the course as per syllabus coverage.

Section-A

MULTIPLE CHOICE QUESTION **20 X 1 = 20 MARKS**

S.NO.	QUESTIONS	CO's
1.	What does DCGI stand for .... a) Drug Centre General of India b) Drug Controller General of India c) Drug Control Government of India d) Drug Code Government of India	CO-1
2.	Orphan drugs are meant for..... a) Life-threatening diseases b) Chronic diseases c) Rare diseases d) Genetic disorders	
3.	Treatment INDs are meant for..... a) Serious & life-threatening conditions b) Commercial use c) Emergency situations d) New indications of already approved drugs	
4.	Generic drugs requires.....for marketing. a) Clinical Trials b) Animal Trials c) Preclinical & Clinical studies d) Bioequivalence studies	
5.	CBER stands for..... a) Center of Biological Emergence & Resurgence b) Center for Biologics Evaluation & Research c) Central Biological Evaluation & Remuneration d) Central Biologics of Education & Research	CO-2
6.	Abbreviated New Drug Applications are filed for..... a) Scheduled drugs b) New Drugs c) Innovator drugs d) Generic drugs	

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7.	The review time period of an INDA by FDA is….. a) 30 b) 45 c) 60 d) 120	
8.	Phase III Clinical trials are also known as…….. a) Human pharmacology b) Therapeutic confirmatory phase c) Therapeutic Exploratory phase d) Post marketing monitoring	
9.	The structure of Common Technical Document is categorized into…..modules. a) 3 b) 7 c) 5 d) 4	
10.	Type III DMFs are meant for…….. a) Excipients b) Packaging Material c) Drug Substance/Drug Product d) Manufacturing sites/facilities	
11.	The Content & structure of Module 4 OF CTD is specified in ICH.....guidelines a) M4 b) M4Q c) M4E d) M4S	CO-3
12.	The full form of eCTD is…….. a) Extended common technical document b) Elongated common technical document c) Electronic common technical document d) Exceeded common technical document	
13.	IEC stands for..... a) Institutional Ethics Committee b) Independent Ethics Committee c) Institutional Ethics Conference d) Independent Ethics Conference	
14.	Pharmacovigilance is the pharmacological science of..... a) Prevention of Adverse effects b) Detection of Adverse effects c) Evaluation of Adverse effects d) All of the above	CO-4
15.	To develop a clinical trial protocol is the GCP obligation of….. a) Sponsor b) Monitor c) Regulatory authority d) Investigator	

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16.	IRB/IEC are committees for…… a) DMF preparation b) Monitoring and managing clinical trials c) Ethics and welfare of human participants in the clinical trials d) Audit of the clinical research center	
17.	Federal Register consists of..... a) Innovator drug b) Rules & regulations c) Generic drugs d) Orphan drugs	CO-5
18.	Purple Book contains: a) Innovator Drugs b) FDA licensed Biological products c) Generic products d) Orphan drugs	
19.	The regulations for the pharmaceutical industries are formed and updated by….. a) Regulatory authority b) CDER c) CBER d) IRB/IEC	
20.	The Orange Book consists of a list of…… a) Innovator Drugs b) FDA licensed Biological products c) Generic products d) Orphan drugs	

Section B

Short Questions: Attempt any seven questions. **7x5 = 35 marks**

S.No.	QUESTIONS	CO's
1.	Write a note on the stages of drug discovery & development.	CO-1
2.	Explain the generic drug product development.	CO-1
3.	Discuss the approval process & timelines involved in an NDA.	CO-2
4.	Give an overview of the regulatory authority of the United States.	CO-2
5.	What is a drug master file, and discuss its types.	CO-3
6.	Discuss the procedure for the export of pharmaceutical products.	CO-3
7.	How are the clinical trial protocols developed?	CO-4
8.	Write a short note on Pharmacovigilance- safety monitoring in clinical trials.	CO-4
9.	Explain the orange book and purple book, and list the major differences.	CO-5

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Section C

Long questions: Attempt any two questions **2x10 = 20 marks**

S.No.	QUESTIONS	CO's
1.	Discuss the organizational structure and types of applications in India.	CO-5
2.	Write down the structure and content of the Common Technical Document.	CO-3
3.	Give a detailed overview of the GCP obligations of investigators, sponsors, and monitors.	CO-4