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

Sessional I (Even) Semester Examination March 2025

Roll no.....

Name of the Course: B.Pharm
Semester: 8th
Name of the Paper: Pharmaceutical Regulatory Science
Paper Code: BP-804 ET
Time: 1.5 hour **Maximum Marks: 30**

Note:
(i) This question paper contains three sections
(ii) All the sections are compulsory

Section-A

MULTIPLE CHOICE QUESTION **10 X 1 = 10 MARKS**

S.N	CONTENTS	CO's
1.	What is the first step in the drug discovery process? A) Clinical Trials B) Target Identification C) Drug Manufacturing D) Market Analysis	CO-1
2.	A new drug successfully passed preclinical testing. What should be the next step? A) Submit an NDA (New Drug Application) B) Conduct Phase I clinical trials C) Start large-scale manufacturing D) Begin post-marketing surveillance	
3.	If a drug has a high bioavailability but a short half-life, what adjustment should be considered? A) Increase the dosage frequency B) Reduce its bioavailability C) Halt further drug development D) Conduct Phase IV trials immediately	
4.	During which clinical trial phase is the drug's efficacy tested on a small group of patients with the disease? A) Phase I B) Phase II C) Phase III D) Phase IV	
5.	What is bioequivalence in generic drug development? A) The drug has the same color and shape as the innovator drug	

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	B) The drug produces the same therapeutic effect at a lower cost C) The drug has the same rate and extent of absorption as the innovator drug D) The drug must be tested on at least 1,000 patients	
6.	Which regulatory agency oversees the IND application process in the United States? A) WHO (World Health Organization) B) EMA (European Medicines Agency) C) FDA (Food and Drug Administration) D) ICH (International Council for Harmonisation)	CO-2
7.	A pharmaceutical company wants to test a new cancer drug on human subjects. What is the first regulatory step? A) Submit a New Drug Application (NDA) B) Conduct Phase 2 clinical trials C) Submit an Investigational New Drug (IND) application D) Conduct post-marketing surveillance	
8.	What is the key difference between an NDA and an ANDA? A) NDA is for new drugs, whereas ANDA is for generic versions of approved drugs B) NDA requires bioequivalence studies, whereas ANDA does not C) NDA is faster to approve than ANDA D) NDA is for over-the-counter (OTC) drugs only	
9.	A company wants to bring a lower-cost version of an off-patent brand-name drug to market. Which regulatory pathway should they follow? A) Submit an NDA B) Submit an ANDA C) File an IND application D) Apply for an OTC Monograph	
10.	Why does an NDA require clinical trials while an ANDA does not? A) NDA drugs are entirely new molecules, whereas ANDA drugs are bioequivalent to existing drugs B) ANDA drugs require higher safety standards than NDA drugs C) NDA approvals are only for over-the-counter drugs D) ANDA applications do not require FDA review	

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Section B

Short questions: Attempt any two. **2x5 = 10 marks**

SN	QUESTIONS	CO's
1.	What are the major steps involved in drug discovery?	CO 1
2.	Define bioequivalence in the context of generic drug development also explain why is bioequivalence testing required for generic drugs?	CO 1
3.	List the three types of IND applications and their purposes.	CO2

Section C

Long questions: Attempt any one **1x10 = 20 marks**

SN	QUESTIONS	CO's
1	Why do innovator drugs have patent protection? How does this impact the availability of generics?	CO1
2	Describe the key differences between a New Drug Application (NDA) and an Abbreviated New Drug Application (ANDA).	CO2