

Programme: B. Pharm

Course: Pharmaceutical Regulatory Science

Course Code: BP804ET

Enrolment no. _____

Full Marks: 75

Time: 3 Hrs.

Q.No.	Questions	CO	Bloom Taxonomy Category	Marks
Section I				
1	Objective Type Questions			
	<p>i. Which of the following is submitted for approval of a generic drug? a. IND b. NDA c. ANDA d. CTD</p> <p>ii. The U.S. regulatory authority for pharmaceuticals is: a. EMA b. MHRA c. FDA d. CDSCO</p> <p>iii. Which CTD module contains clinical study reports? a. Module 1 b. Module 2 c. Module 3 d. Module 5</p> <p>iv. Which module of CTD includes Quality information (chemistry, manufacturing, and controls)? a. Module 2 b. Module 3 c. Module 4 d. Module 5</p> <p>v. Which of the following is not a part of the Common Technical Document (CTD)? a. Administrative and product information b. Clinical summaries c. Animal pharmacology studies d. Marketing campaign details</p> <p>vi. Informed consent is obtained from participants: a. Before the clinical trial begins b. After the trial ends c. Only in Phase IV d. When results are published</p> <p>vii. The person responsible for supervising the conduct of the clinical trial at a site is known as the: a. Auditor b. Subject c. Investigator d. Sponsor</p> <p>viii. Which document contains details about the purpose, methodology, and ethical considerations of a trial? a. Drug Master File b. Informed consent form c. Trial protocol d. Investigator brochure</p> <p>ix. Which term refers to continuous monitoring of drug safety post-approval? a. Bioequivalence testing b. Good Manufacturing Practice c. Pharmacovigilance d. Preclinical trials</p> <p>x. Which of the following is a legally binding rule issued by a regulatory authority? a. Guidance b. Regulation c. Recommendation d. Opinion</p> <p>xi. Which publication is used for biological product listings and biosimilar approvals? a. Orange Book b. Federal Register c. Code of Federal Regulations d. Purple Book</p> <p>xii. Which book helps determine if a generic product is therapeutically equivalent to a brand-name drug? a. Orange Book b. Purple Book c. Red Book d. Blue Book</p> <p>xiii. The Common Technical Document (CTD) format was developed by: a. FDA b. WHO c. ICH (International Council for Harmonisation) d. EMA</p> <p>xiv. Which of the following documents contains confidential information about manufacturing and controls of a drug substance? a. NDA b. DMF (Drug Master File) c. IND d. ANDA</p> <p>xv. Which regulatory authority governs pharmaceutical products in Japan? a. EMA b. PMDA c. FDA d. CDSCO</p> <p>xvi. Which of the following is a responsibility of the sponsor in a clinical trial? a. Conducting routine inspections b. Overseeing drug marketing c. Initiating and funding the clinical trial d. Dispensing medicines at pharmacies</p> <p>xvii. The Code of Federal Regulations (CFR) is best described as: a. A list of pharmaceutical companies b. A compilation of laws and regulations of the U.S. government c. A list of biologics d. A guideline for patent applications</p> <p>xviii. Which of the following is governed by specific Acts and Laws? a. Clinical practices b. Drug regulation c. Good manufacturing practices d. All of the above</p> <p>xix. The term "guideline" in regulatory science refers to: a. A mandatory rule b. A type of regulation c. A general principle or recommendation d. A patent law</p> <p>xx. Which of the following is required for the export of pharmaceutical products? a. WHO GMP certification b. ANDA approval c. IND submission d. Phase IV data</p>	CO1	Remember	1 x 20 = 20

Section II			
2. Short Answer type questions.			
a	What are the reason behind the non-clinical studies before clinical administered?	CO1	Remember
b	Describe the key features of an Abbreviated New Drug Application (ANDA).	CO2	Remember
c	Explain the importance of technical documentation in international drug registration.	CO3	Understand
d	Outline the monitoring responsibilities during a clinical trial.	CO4	Apply
e	Explain the structure of the Code of Federal Regulations (CFR).	CO5	Understand
f	Discuss the structure and responsibilities of an Institutional Review Board (IRB).	CO4	Understand
	or		
	Write a short note on monitor's responsibilities.	CO4	Understand
g	Outline the procedure for export of pharmaceutical products from India.	CO3	Understand
	or		
	How does eCTD improve regulatory submission efficiency?	CO3	Apply
Section III			
Long Answer Type questions			
3	Evaluate the challenges faced by pharmaceutical companies in shifting from innovator products to generics.	CO1	Evaluate
	or		
	Create a flowchart depicting the entire process of drug discovery and development from molecule identification to market launch.	CO1	Create
4	Create a comparative table of regulatory documents and publications (Federal Register, CFR, Orange Book, and Purple Book) with their uses.	CO5	Create
	or		
	Explain the importance of understanding regulatory terminologies for a regulatory affairs professional.	CO5	Evaluate

Course Outcomes (CO):

CO1: To understand the concept, basic principles and ethics of Pharmaceutical Marketing.

CO2: To develop the ability to analyze customer behavior and Market research.

CO3: To apply the knowledge for selection of targeted customer and to take appropriate product decision

CO4: To develop modern tools, communication skills, Planning skills and leadership skills so as to become successful marketing professional.

CO5: To understand need of the society with respect to pharmaceutical Products and understand rural marketing and Global Marketing