JHARKHAND Rai University
RANCHI

End Semester/Reappear (Semester VII) Examination Dec 2024

Programme: B. Pharm
Course: Industrial Pharmacy-II **Full Marks: 75**
Course Code: BP702T **Time: 3 Hrs.**
Enrolment no. _____

Q.No.	Questions	CO	Bloom Taxonomy Category	Marks
	Section I			
1	**Objective Type Questions**			
	i. What does TQM stand for in the context of quality management? a) Total Quality Measurement b) Total Quality Management c) Transcendental Quality Management d) Total Quality Manufacturing ii. Which of the following is NOT a key element of TQM? a) Focus on the customer b) Employee involvement c) Cost reduction d) Continuous improvement iii. What type of customers are employees who receive the output of other employees within an organization? a) External customers b) Internal customers c) Intermediate customers d) Tertiary customers iv. Which of the following is NOT a key aspect of QbD as outlined in the sources? a) Target Product Profile (TPP) b) Critical Quality Attributes (CQAs) c) Cost Analysis d) Risk Assessment v. What does the acronym DMAIC stand for in the Six Sigma methodology? a) Define, Measure, Analyze, Improve, Control b) Design, Manufacture, Assemble, Inspect, Correct c) Develop, Market, Analyze, Innovate, Control d) Discover, Measure, Analyze, Implement, Certify vi. Who issues the COPP? a) The importing country's health authority b) The exporting country's health authority c) The World Health Organization d) The Marketing Authorization Holder vii. Which document is NOT required to obtain a COPP? a) GMP certificate b) Manufacturing License c) Clinical trial data d) Last approved SPC viii. What is the role of the CDSCO in India? a) To provide marketing strategies for drugs b) To regulate the import and export of pharmaceuticals c) To conduct clinical trials d) To issue patents for new drugs ix. Which module contains administrative/legal information in the CTD? a) Module I b) Module II c) Module III d) Module IV x. What is the purpose of periodic inspections of manufacturing plants? a) To assess financial performance b) To ensure compliance with GMP c) To evaluate marketing strategies d) To conduct clinical trials xi. What is the primary goal of Regulatory Affairs (RA) in the pharmaceutical industry? a) Minimizing production costs for pharmaceuticals. b) Protecting public health by ensuring the safety, quality, and efficacy of pharmaceutical products. c) Maximizing profits for pharmaceutical companies. d) Accelerating the drug development process without regard to safety regulations. xii. Which of the following is NOT a core area involved in the regulation of drug products? a) Pharmacovigilance (monitoring adverse drug reactions) b) Drug registration c) Manufacturing processes d) Advertising and marketing strategies xiii. Which of the following regulatory agencies is responsible for drug approvals in the European Union? a) USFDA b) EMA c) TGA d) CDSCO xiv. What was the primary objective behind the formation of the International Council for Harmonization (ICH)? a) To standardize drug pricing globally. b) To harmonize technical requirements for pharmaceutical registration to ensure drug safety, efficacy, and quality worldwide. c) To create a single global regulatory agency to replace individual country-specific agencies. d) To promote the interests of pharmaceutical companies in regulatory decision-making. xv. During the development phase of a drug, which of the following is NOT a key role of the Regulatory Affairs department? a) Seeking scientific advice from regulatory authorities. b) Optimizing submission strategies for regulatory dossiers. c) Conducting clinical trials to gather data on the drug's efficacy. d) Ensuring compliance with all relevant legislative requirements.	CO1	Remember	**1 x 20 = 20**

	xvi. What is "Technology Transfer"? a. The process of patenting new drug discoveries b. The legal framework for pharmaceutical production c. The transition of a drug from discovery to commercial production d. The sharing of profits from drug sales xvii. According to the World Health Organization (WHO), what is a crucial factor for successful technology transfer? a. Identical facilities and equipment between the sending and receiving units. b. A strong focus on financial profits over quality aspects. c. A documented and planned approach with trained personnel and a quality system. d. Minimizing communication between the sending and receiving units. xviii. What is a "Technical Gap Analysis" in the context of technology transfer? a. A comparison of financial investments between two companies b. An assessment of the differences in technical capabilities between the sending and receiving units c. A review of marketing strategies for a new drug d. A study of patient responses to a drug in clinical trials xix. Which of the following is a key document used in technology transfer? a. Patent application b. Marketing brochure c. Technology Transfer Protocol d. Clinical trial repo xx. Which of the following is NOT a stage in the typical Quality Risk Management process? a. Risk assessment b. Risk acceptance c. Risk elimination d. Risk review			
Section II				
2. Short Answer type questions.				**7 x 5 = 35**
a	What factors should be considered when transferring a process from R&D to production?	CO1	Remember	
b	What is the purpose of an analytical methods transfer protocol in technology transfer?	CO2	Understand	
c	Name three major regulatory agencies involved in drug approval.	CO3	Remember	
d	What type of organizations can apply the ISO 14001 standard?	CO4	Understand	
e	What is the purpose of Module I in the Common Technical Document (CTD)?	CO5	Understand	
f	What is the purpose of the Certificate of Pharmaceutical Product (COPP)?	CO5	Understand	
	or			
	What is the role of the World Health Organization (WHO) in drug regulation?	CO5	Remember	
g	How continuous improvement be achieved in an organization?	CO4	Understand	
	or			
	What does NABL stand for and what is its purpose?	CO4	Remember	
Section III				
Long Answer Type questions				**2 x 10 = 20**
3	Evaluate the key considerations for transferring process, packaging, and cleaning procedures from R&D to production. How do these considerations ensure the maintenance of product quality and regulatory compliance?	CO1	Evaluate	
	or			
	Explain the role of quality risk management in technology transfer. How do the principles and methodologies of risk management ensure the quality and safety of the transferred product?	CO1	Analyze	
4	Evaluate the function of scale-up studies such as blending and drug layering, in ensuring the efficiency and quality of technology transfer from R&D to full-scale production. Why is it essential to maintain geometric and dynamic similarities in scale-up?	CO2	Evaluate	
	or			
	Compare and contrast the roles of the Sending Unit (SU) and the Receiving Unit (RU) in the technology transfer process. Why it is critical for both units to work in alignment and what might be the impact of mis-alignment?	CO2	Analyze	

Course Outcomes (CO):

CO1: Know the process of pilot plant and scale up of pharmaceutical dosage forms
CO2: Understand the process of technology transfer from lab scale to commercial batch
CO3: Know different Laws and Acts that regulate pharmaceutical industry.
CO4: Understand the approval process and regulatory requirements for drug products
CO5: Understand the Indian regulatory requirements and approval procedures for New Drugs.