JHARKHAND Rai University
RANCHI

End Semester/Reappear (Semester VI) Examination May 2025

Programme: B. Pharm
Course: Quality Assurance **Full Marks: 75**
Course Code: BP606T **Time: 3 Hrs.**
Enrolment no. _____

Q.No.	Questions	CO	Bloom Taxonomy Category	Marks
	Section I			
1	**Objective Type Questions**			**1 x 20 = 20**
	i.Which of the following is a primary risk addressed by cGMP? a) Drug pricing b) Patent expiration c) Mix-ups and cross-contamination d) Lack of skilled manpower ii.Which document is filed with the FDA to begin clinical trials? a) NDA b) ANDA c) INDA d) API iii.Which of the following is NOT a regulatory body? a) FDA (USA) b) CDSCO (India) c) ISO (International) d) MHRA (UK) iv.Which airlock type is designed to maintain high pressure inside compared to both outer areas? a) Cascade b) Sink c) Bubble d) Laminar v.Which area must have independent air handling systems in a pharmaceutical plant? a) Office b) Storage c) QC Laboratory d) Reception	CO1	Remember	
	vi.What must be done to personnel before being hired in a beta-lactam antibiotic facility? a) Eye test b) Tuberculosis test c) Sensitivity test for penicillin d) COVID-19 test vii.What is the minimum acceptable pressure differential between clean and less-clean areas? a) 1 Pa b) 3 Pa c) 5 Pa d) 25 Pa viii.A container used for ampoules is tested using which of these? a) Thermal shock test b) Leak detection test c) Tensile strength d) Tare weight analysis ix.Which test ensures that glass does not release alkali? a) Arsenic test b) Hydrolytic resistance test c) Annealing test d) Seal integrity test x.Which of the following is tested for rubber closures? a) Burst strength b) Rub resistance c) Reducing substances d) Moisture vapor permeability			
	xi. Which agency introduced the concept of validation? a) WHO b) CDSCO c) US FDA d) EMA xii.According to CDSCO, which recall class involves a potential for serious adverse health effects or death? a) Class III b) Class I c) Class II d) Class IV xiii.Which method involves rendering waste into an inert solid mass using cement and lime? a) Autoclaving b) Inertization c) Microwaving d) Chemical disinfection xiv.Which of the following is NOT a type of pharma document? a) SOP b) Invoice c) MFR d) BMR xv. What is the main purpose of calibration in pharmaceuticals? a) To manufacture drugs b) To increase shelf life c) To ensure accurate and reliable measurements d) To clean equipment			
	xvi.Which type of validation is done before routine production starts? a) Concurrent b) Retrospective c) Prospective d) Periodic xvii.Which of the following parameters is NOT included in method validation? a) Accuracy b) Efficiency c) Linearity d) Specificity xviii. Which one is a warning sign during goods receipt? a) Fresh seal b) Tampered temperature tags c) Label match d) Good outer packaging xix.Which waste type is potentially dangerous due to ignitability or toxicity? a) Inert substances b) Non-hazardous waste c) Biomedical waste d) Hazardous waste xx.Blister pack testing includes: a) Vertical load test b) Fragmentation c) Leakage test d) Ash content			

Section II				
2. Short Answer type questions.				**7 x 5 = 35**
a	Explain the principles of Total Quality Management system.	CO1	Understand	
b	What are the importance of training for the establishment of new pharmaceutical industry?	CO2	Understand	
c	Describe the method for testing drug containers as per Indian Pharmacopoeia.	CO3	Understand	
d	What are the types of product's complaint?	CO4	Remember	
e	Define the terms calibration, qualification and validation in the pharmaceutical industry.	CO5	Remember	
f	Explain the steps involved in testing of powdered glass.	CO3	Understand	
	or			
	Describe the responsibilities of personnel in a non-clinical testing facility.	CO3	Understand	
g	Describe the role of quality review in continuous process verification.	CO4	Understand	
	or			
	Describe the role of calibration for pharmaceutical laboratory equipment.	CO4	Understand	
Section III				
Long Answer Type questions				**2 x 10 = 20**
3	Analyze the role of in-process quality control in minimizing production errors.	CO1	Analyze	
	or			
	Create a flowchart for a quality audit in a pharmaceutical plant.	CO1	Create	
4	Analyze the consequences of improper storage and labeling of raw materials.	CO2	Analyze	
	or			
	Evaluate the effectiveness of a training program in preventing cross-contamination.	CO2	Evaluate	

Course Outcomes (CO):

CO 1. To know about Total Quality Management (TQM), ICH Guidelines, Quality by design (QbD), ISO 9000 & ISO14000, NABL accreditation

CO 2: To know about Organization and personnel, Premises, equipment and raw materials

CO 3: To know about Quality Control, Good Laboratory Practices

CO 4: To know about Complaints, Document maintenance in pharmaceutical industry.

CO 5: To know about Calibration and Method Validation, Warehousing.