Name: **Enrolment No:**	

UPES

End Semester Examination, May 2024

Course: Quality Assurance **Semester: VI**
Program: B. Pharm **Duration: 03 Hours**
Course Code: BP606T **Max. Marks: 75**
Instructions: No additional material like graph paper, log table, *etc* is allowed for this examination.

SECTION A

(20 Q x 1 M = 20 Marks)

S. No.	Attempt all questions from section A.	Marks	COs
Q 1	A customer can express his/her dissatisfaction through a) voice b) exit c) both, option a and b d) none of the above	**1**	**CO1**
Q 2	Define class I recall.	**1**	**CO1**
Q 3	Storage condition for long term stability testing of drug substances intended for storage in a refrigerator is: a) 5°C ± 3°C b) 8°C ± 1°C c) -20°C ± 2°C/ 60± 5% RH d) 25°C ± 2°C/ 60 ± 5% RH	**1**	**CO1**
Q 4	NABL is: a) National Accreditation Board for Testing and Calibration b) New Accreditation Board for Laboratories c) National Accreditation Board for Laboratories d) National Accreditation Board for Limit	**1**	**CO1**
Q 5	Which of the following statement is correct? a) QA ensures that the product quality is of the required quality. b) GMP ensures that the products are consistently manufactured to an appropriate quality. a) QC is concerned with the sampling, specification, testing, documentation, and release procedures. b) All of the above.	**1**	**CO1**
Q 6	Which one of the following is NOT a correct statement for Richard Muther's systematic layout planning? a) In the closeness rating chart, the rating for department A relative to department B is similar to the rating of department B to department A. b) A grid (closeness rating chart) displays the ratings of the relative importance of the distance between different departments of an organization. c) The composite movements (back-and-forth movement) of the unit load between the departments is calculated and then ranked from the highest to lowest movement. d) Closeness ratings are given to departments in the form of codes, which depict the desired closeness of the departments according to the relative strength of their closeness.	**1**	**CO3**
Q 7	Headquarter of ISO is located at: a) Maryland, Montgomery County b) Nancy, France c) Geneva, Switzerland	**1**	**CO3**

	d) Mumbai, India		
Q 8	ISO was formed in: a) 1947 b) 1988 c) 1917 d) 1817	**1**	**CO3**
Q 9	In 1937, 107 people in the United States died of diethylene glycol poisoning following the use of: a) sulfanilamide elixir b) compound benzaldehyde c) both a and b d) none of the above	**1**	**CO3**
Q 10	Which one of the following is not an elements of material management? a) Calculate from the trends in Consumption during last 2 years. b) Demand estimation. c) Estimation of reuse of recalled material. d) Identify the needed items.	**1**	**CO3**
Q 11	Write any two sources of contamination in pharmaceutical manufacturing area.	**1**	**CO3**
Q 12	Economic order of quantity (EOQ) is calculated by below formula: a) EOQ = Average monthly consumption ÷ Lead time [in months] + Buffer stock + Stock on hand b) EOQ = Average monthly consumption - Lead time [in months] - Buffer stock + Stock on hand c) EOQ = Average monthly consumption X Lead time [in months] + Buffer stock – Stock on hand d) All of the above	**1**	**CO3**
Q 13	Which of the below statement is correct in case of inventory control? a) 'A' items are small in number, but consume lesser amount of resources b) 'A' items are large in number, but consume lesser amount of resources c) 'C' items are large in number, but consume small amount of resources d) All of the above	**1**	**CO4**
Q 14	Define limit of detection.	**1**	**CO4**
Q 15	Efficiency of HEPA filter is _____% for particles of _____ size.	**1**	**CO4**
Q 16	Define operational qualification (OQ).	**1**	**CO4**
Q 17	ICH Q9 guidelines are intended for _____. a) quality risk management b) determination of impurities in new drug substances c) determination of residual solvents d) validation of analytical procedures	**1**	**CO5**
Q 18	The scope of ICH Q3A (R2) guidelines is to determine: a) impurities in new drug substances b) residual solvents c) validation of analytical procedures d) none of the above	**1**	**CO5**
Q 18	Therapeutic Goods Administration (TGA) is the regulatory body of a) Australia b) Germany c) South Africa d) Japan	**1**	**CO5**

Q 20	Below is the correct statement about ISO-14001: a) ISO-14001 outlines 18 elements and these 18 elements are divided into 6 clauses. b) ISO-14001 outlines 6 elements and these 6 elements are divided into 18 clauses. c) ISO 14001 is a series of standards and development published by the ISO that define, establish, and maintain an effective quality assurance system for manufacturing and service industries. d) None of the above.	**1**	**CO5**
SECTION B (20 Marks) **(2 Q x 10 M = 20 Marks)**			
	Attempt any two questions from section B.	**Marks**	
Q 1	Define validation. Write in detail about various types of equipment validations.	**2 + 8**	**CO4**
Q 2	Define inventory control. Explain ABC and VED analysis approaches of inventory control.	**2+4+4**	**CO2**
Q 3	Enlist objectives of ICH guidelines. Classify ICH stability zones. Describe ICH guidelines for the stability testing of drug product intended to be stored under room temperature, refrigeration temperature, and in a freezer.	**2+2+6**	**CO5**
SECTION-C (35 Marks) **(7 Q x 5 M = 35 Marks)**			
	Attempt any seven questions from section C.	**Marks**	
Q 1	Classify and explain various types of complaints of pharmaceutical products.	**5**	**CO1**
Q 2	Explain various responsibilities of quality assurance personal in pharmaceutical industries.	**5**	**CO1**
Q 3	Write a note on importance of personnel training in pharmaceutical industries.	**5**	**CO1**
Q 4	Explain various points that need to be noted before the purchase of equipment.	**5**	**CO2**
Q 5	Define master formula record. Explain various information that should be mentioned in a master formula record.	**2+3**	**CO2**
Q 6	Discuss various responsibilities of quality control department in a pharmaceutical industry.	**5**	**CO3**
Q 7	Write a note on storage and retrieval of records and data in a pharmaceutical manufacturing unit.	**5**	**CO3**
Q 8	Explain Brown-Gibson model for equipment selection.	**5**	**CO4**
Q 9	Differences between quality assurance and quality control system in pharmaceutical industries.	**5**	**CO5**