Name: Enrolment No:	

UPES Dehradun
End Semester Examination May 2025

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	ISO 9001 primarily focuses on which of the following core elements? a) Quality policy b) Quality documentation c) Quality audit d) Quality review	**1**	**CO1**
Q 2	What are the key principles of GMP? a) Product packaging and marketing b) Ensuring consistent product quality and controlling cross-contamination and mix-ups c) Product branding d) Cost-effectiveness of production	**1**	**CO1**
Q 3	Which act in England, passed in 1540, initiated the inspection of medicines? a) The Medicines Act b) The Drugs and Cosmetics Act c) Apothecaries Wares, Drugs and Stuffs Act d) British Pharmacopoeia Act	**1**	**CO1**
Q 4	Which type of glass is suitable for storing acidic and neutral aqueous preparations for parenteral use? a) Type I – Borosilicate glass b) Type II – Treated soda lime glass c) Type III – Soda lime glass d) Type IV – General-purpose glass	**1**	**CO1**
Q 5	Which regulatory authority is responsible for drug regulation in India? a) FDA b) EMEA c) CDSCO d) TGA	**1**	**CO2**
Q 6	Which of the following department holds responsibility for quality monitoring and audits in the pharmaceutical industry? a) Regulatory affair b) Quality control c) Quality assurance d) Production	**1**	**CO2**
Q 7	Below is the correct sequence to handling complaints in the pharmaceutical industry: a) Receiving complaint, Investigation, corrective actions, feedback to customer, Trend analysis by QC b) Investigation, Receiving complaint, corrective actions, Trend analysis by QC, feedback to customer	**1**	**CO2**

	c) Receiving complaint, Trend analysis by QC, Investigation, feedback to customer, corrective actions d) Receiving complaint, feedback to customer, Trend analysis by QC, corrective actions, Investigation		
Q 8	What is considered a subjective criterion in the Brown-Gibson model? a) Cost of labor b) Physical appearance c) Availability of spares d) Maintenance frequency	**1**	**CO2**
Q 9	What is the purpose of using different disinfectants in rotation in cleanrooms? a) To reduce cost b) To make the room smell fresh c) To prevent development of resistant microorganisms d) To increase shelf life of products	**1**	**CO3**
Q 10	What is a critical requirement to avoid overlaps and gaps in responsibilities? a) Job rotation b) Verbal instructions c) Written job descriptions d) Frequent meetings	**1**	**CO3**
Q 11	What is the purpose of specific training for personnel working in clean or high-risk areas? a) To increase salary b) To improve manufacturing speed c) To reduce risk of contamination and exposure d) To reduce documentation load	**1**	**CO3**
Q 12	Reference standard for preparing batch manufacturing record by a manufacturing unit is a) Quality audit b) Master Formula records c) Standard Operating Procedure d) All of the above	**1**	**CO3**
Q 13	Clean rooms are classified according to the a) Airchecks/ hour b) Material being processed e) Number & size of particles permitted per volume of air a) All of above	**1**	**CO3**
Q 14	What is the minimum pressure differential required between the manufacturing area and the support areas? a) 15 pascals b) 25 pascals c) 50 pascals d) 100 pascals	**1**	**CO3**
Q 15	According to ICH guidelines, how many primary batches are recommended for photostability testing? a) At least 1 b) At least 2 c) At least 3 d) At least 4	**1**	**CO3**
Q 16	Process control is carried out a) During production c) After production b) Before product d) All of the above	**1**	**CO3**

Q 17	During validation, at least _____ batches should be tested, and at least _____ tests should be carried out for each sample. a) 6, 3 b) 3, 2 c) 3, 3 d) 1, 1	**1**	**CO4**
Q 18	Which of the following best represents the core principles of Total Quality Management (TQM)? a) Focus on customer b) Continuous improvement c) Employee involvement d) All of the above	**1**	**CO4**
Q 19	ICH Q1A(R2) guideline specifically deals with: a) Good Manufacturing Practices b) Stability Testing of New Drug Substances and Drug Products c) Genotoxicity Testing d) Bioequivalence Studies	**1**	**CO4**
Q 20	Type A complaints do not include: a) Purity and safety b) Potency c) Product stability d) Extraneous contamination, mix ups *etc*.	**1**	**CO4**
SECTION B (20 Marks) **(2 Q x 10 M = 20 Marks)**			
	Attempt any two questions from section B.	**Marks**	
Q 1	Enlist four categories of ICH topics. Describe the testing frequency and storage conditions for the stability testing of drug product that are stored under room temperature, in refrigerator, and in freezer.	**2+8**	**CO1**
Q 2	Define validation. Draw Ishikawa Diagram (Fish Bone Diagram). Write in detail about cleaning validation.	**2+2+6**	**CO2**
Q 3	What are general considerations followed for equipment selection? Enlist various factors affecting equipment selection. Describe Brown-Gibson model for equipment selection.	**2+2+6**	**CO4**
SECTION-C (35 Marks) **(7 Q x 5 M = 35 Marks)**			
	Attempt any seven questions from section C.	**Marks**	
Q 1	What is Total Quality Management? Explain various elements of Total Quality Management.	**1+4**	**CO1**
Q 2	Describe the process of handling of complaints and their evaluation in pharmaceutical industries.	**5**	**CO2**
Q 3	Classification and explain various packaging defects.	**5**	**CO3**
Q 4	Explain quality audit in pharmaceutical manufacturing industries.	**5**	**CO3**
Q 5	Enlist various sources of contamination in a sterile formulation area. What are various approaches used to prevent contamination in an aseptic area?	**2+3**	**CO4**
Q 6	Enlist any two unfortunate events that lead to the development of GLP regulations. Write a note on “Industrial Bio Test” laboratory case.	**2+3**	**CO5**
Q 7	Describe the protocol for conduct of a non-clinical laboratory study.	**5**	**CO5**
Q 8	Explain materials management approach in a pharmaceutical manufacturing facility.	**5**	**CO5**
Q 9	What are the possible grounds for the disqualification of testing facilities? What are the consequences of noncompliance of GLP regulations?	**2+3**	**CO5**