T.Y. B. Pharm
Sem - VI
10/11/2025
ATKT

Duration: 3 Hrs **Total marks: 75**

N.B.: 1. All questions are compulsory
2. Figures to right indicate full marks

Q. I Choose appropriate option for the following multiple choice-based questions. 20

1 Quality risk management falls under which ICH guideline?
   a. Q3
   b. Q9
   c. Q10
   d. Q12

2 According to WHO GMP guidelines, which is the most critical requirement for sterile product manufacturing?
   a. Use of high-efficiency particulate air (HEPA) filters
   b. Raw material cost reduction
   c. Storage of sterile products at low temperature
   d. Availability of at least 10 trained personnel in the cleanroom

3 In a stability study under ICH guidelines, what are the recommended conditions for long-term stability testing for a drug substance stored at controlled room temperature?
   a. 40°C ± 2°C / 75% RH ± 5% RH
   b. 35°C ± 2°C / 65% RH ± 5% RH
   c. 25°C ± 2°C / 60% RH ± 5% RH
   d. 5°C ± 3°C

4 Which of the following tests is performed to assess the print quality on secondary packaging materials?
   a. Smear resistance test
   b. Water attack test
   c. Impact resistance test
   d. Tensile strength test

5 The buildings used for the manufacture of drugs should conform to all the conditions laid down in _____.
   a. Pharmacy Act
   b. Factories Act
   c. Trade Marks Act
   d. Companies Act

6 What is the primary purpose of pharmaceutical warehousing?

a. To store excess raw materials indefinitely
b. To ensure safe and compliant storage of pharmaceutical products before distribution
c. To increase product pricing by limiting stock availability
d. To eliminate the need for Good Storage Practices (GSP)

7 This is **not** the type of maintenance_____.

a. Breakdown maintenance
b. Corrective maintenance
c. Predictive maintenance
d. Physical maintenance

8 Which is the second step in Handling of complaints?

a. Monthly trend analysis
b. Corrective action
c. Technical investigation
d. Receiving of complaints

9 In "Quality by Design", what does QTPP stand for?

a. Quality target Product profile
b. Quantity Target Process Profile
c. Quantity Target Product Profile
d. Quality Target Process Profile

10 What is the primary purpose of personnel training in a pharmaceutical company?

a. To increase company profits
b. To ensure compliance with Good Manufacturing Practices (GMP)
c. To reduce the need for quality control
d. To limit the number of employees required

11 The term 'Disqualification of Testing Facilities' in GLP refers to:

a. a) The suspension of a facility's accreditation due to non-compliance
b. b) The transfer of study responsibility to another facility
c. c) The closing down of a facility due to financial reasons
d. The elimination of certain tests from a study

12 _____ test is specifically used for testing glass containers used for aqueous parenteral preparations.

a. Light transmission test
b. Arsenic test
c. Thermal Shock test
d. Internal bursting pressure test

13 During pharmaceutical validation, what is the primary purpose of an Operational Qualification (OQ)?

a. Monitoring long-term performance of the system
b. Verifying production capacity
c. Checking if the equipment operates within defined parameters
d. Ensuring the equipment is installed correctly

14 Which of the following tests is performed to evaluate the chemical resistance of glass containers?

a. Light transmission test
b. Water attack test
c. Karl Fischer test
d. Gas chromatography

15 Which type of airflow is used in clean rooms to prevent contamination?

a. Turbulent airflow
b. Unidirectional (Laminar) airflow
c. Recirculatory airflow
d. Static airflow

16 GLP primarily applies to:

a. Clinical trials in humans
b. Nonclinical laboratory studies for product safety evaluation
c. Marketing of pharmaceutical products
d. Manufacturing and packaging processes

17 Which type of glass is most suitable for storing parenteral formulations?

a. Type I Borosilicate glass
b. Type II Soda-lime glass
c. Type III Soda-lime silica glass
d. Type IV General-purpose glass

18 Which document provides detailed instructions on how to manufacture a product in a batch-wise manner?

a. Master Formula Record (MFR)
b. Standard Operating Procedure (SOP)
c. Quality Audit Report
d. Stability Study Report

19 What is the primary purpose of raw material quarantine?

a. To separate materials that require quality testing before approval
b. To store materials permanently in one location
c. To discard unnecessary materials
d. To prepare materials for immediate use

20 Which tool is commonly used in QbD for risk assessment?

a. Fishbone (Ishikawa) diagram
b. X-ray Diffraction (XRD)
c. Differential Scanning Calorimetry (DSC)
d. High-Performance Liquid Chromatography (HPLC)

Q. II Answer any two questions. (Any 2) **20**

1 Elaborate on Q1A and Q1B ICH guidelines for new drug substances. **10**

2 Define GLP. What is the role of Quality Assurance Unit in a testing facility? Discuss in brief the hydrolytic resistance test. **10**

3 What is Complaint? Discuss the steps involved in handling of complaints in a pharmaceutical company. **10**

Q. III Answer any seven questions (Any Seven) **35**

1 Explain the elements of Total Quality Management (TQM). **5**

2 Discuss the QC tests for rubber closures. **5**

3 Explain the role of batch formula records and master formula records in pharmaceutical documentation. **5**

4 Define QbD. Elaborate on tools of Qbd. **5**

5 Write a note on utilities and maintenance of sterile areas. Illustrate a layout of Capsule manufacturing unit. **5**

6 Define validation. Explain in brief the types of process validation. **5**

7 Define Quality Audit and Quality Review and differentiate between them. **5**

8 Write in brief about personal training. Discuss the responsibilities of key personnel. **5**

9 Discuss the Good warehousing practices in detail. **5**

****