T.Y. B. Pharm
Sem - VI
30/04/2025

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 As per 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

2 Service bay is maintained at _____.
   a. Class 100
   b. Class 200
   c. Class 500
   d. Class 1000

3 Following are tools of QbD except _____.
   a. Critical Quality Attributes
   b. Process Analytical Technology
   c. Risk assessment
   d. Design of Experiments

4 Grammage is used to determine the physical dimensions of the _____ material.
   a. Thermosetting plastic
   b. Paper and paperboard
   c. Glass
   d. Metal

5 The efficiency of HEPA filters should be _____ at 0.22micron particle size.
   a. 95.55%
   b. 99.99%
   c. 93.22%
   d. 90.99%

6 What is the purpose of a Retrospective Validation study?
   a. To validate new processes before production
   b. To evaluate existing products based on historical data
   c. To determine batch release criteria
   d. To eliminate the need for process qualification

7 _____ help the managers to make salary revisions, allowances and other benefits related to salaries.

a. Audit records
b. Deviation records
c. Personal records
d. Master records

8 The main reason for product recalls in the pharmaceutical industry is:

a. Manufacturing process changes
b. Poor sales performance
c. Adverse reactions or product defects
d. Expiry date approaching

9 Maintaining reference standard and retained samples is the responsibility of _____ department.

a. Stores
b. Quality Assurance
c. Production
d. Quality Control

10 Repairing tablet press machine with broken cam is _____.

a. Preventive maintenance
b. Predictive maintenance
c. Corrective maintenance
d. Curative maintenance

11 In the test for volatile sulphides in rubber closure, _____ paper is used

a. Litmus paper
b. Starch paper
c. Lead acetate paper
d. Mercuric chloride

12 The _____ is responsible for the conduct of a nonclinical laboratory study.

a. Study Director
b. Scientist
c. Quality Assurance Unit
d. Laboratory Technician

13 In warehouse management, FIFO (First In, First Out) is used to:

a. Ensure older stock is used before newer stock
b. Reduce cost of storage
c. Increase production speed
d. Minimize the requirement for stability testing

14 The OECD stands for
   a. Organization for Environmental Coordination and Discussion
   b. Organization for Economic Cooperation and Development
   c. Organization for Economic Cooperation and Discussion
   d. Organization for Environmental Cooperation and Development

15 Toilets should not be in contact directly with _____ area.
   a. Production
   b. Reception
   c. Administrative office
   d. Locker room

16 As per USFDA GLP guidelines, Subpart C is _____.
   a. Equipment
   b. Organization and personnel
   c. Records and Reports
   d. Facilities

17 _____test is specifically used for testing glass containers used for aqueous parenteral.
   a. Light transmission test
   b. Arsenic test
   c. Thermal Shock test
   d. Internal bursting pressure test

18 What is the primary purpose of a Product Quality Review (PQR) in pharmaceutical companies?
   a. To analyze trends in complaints and recall data
   b. To track production costs
   c. To compare product sales across different regions
   d. To generate financial reports for investors

19 The buildings used for the manufacture of drugs should conform to all the conditions laid down in _____.
   a. Pharmacy Act
   b. Factories Act
   c. Drug and Cosmetic Act
   d. Companies Act

20 What is the validity period of NABL accreditation once granted?
   a. 1 year
   b. 2 years
   c. 3 years
   d. 5 years

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

1 Define GLP. What is the role of Quality Assurance Unit in a testing facility? Write in brief about animal care for conduct of nonclinical study. **10**

2 Define TQM & write a note on elements and principles of TQM. Give the process for NABL accreditation. **10**

3 Define recall. Explain the process of recall. Write a note on disposal of waste in pharmaceutical industry. **10**

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

1 Enlist the participants of ICH. Write in brief about photostability testing of drug products. **5**

2 Enlist the quality control tests for glass containers. Write in brief about powdered glass test. **5**

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

4 Define QbD. Explain the key elements of QbD **5**

5 Explain the design and construction of building for a pharmaceutical manufacturing unit. **5**

6 Describe Good Warehousing Practices and its importance in pharmaceutical materials management. **5**

7 Define SOP. Explain the general format of SOP and its implementation. **5**

8 Explain in detail the maintenance of stores for raw materials. Illustrate a layout for raw material stores in a pharmaceutical manufacturing unit. **5**

9 Define Validation. Give the process for qualification of UV-visible spectrophotometer. **5**

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