

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 Good Manufacturing Practice is a part of ICH _____ guidelines.
 - a. Quality
 - b. Safety
 - c. Efficacy
 - d. Multidisciplinary
- 2 Air pressure differentials in a clean room should be checked _____.
 - a. Daily
 - b. Yearly
 - c. Biannually
 - d. Weekly
- 3 _____ used to help to determine whether there is a correlation between two factors.
 - a. Fishbone diagram
 - b. Control charts
 - c. Scatter graphs
 - d. Check sheets
- 4 The _____ is responsible for the conduct of a nonclinical laboratory study.
 - a. Laboratory Technician
 - b. Scientist
 - c. Study Director
 - d. Quality Assurance Unit
- 5 The dispensing of raw materials from Stores must follow the principle of _____.
 - a. First Out Then In
 - b. Fast Out Fast In
 - c. Fast In Fast Out
 - d. First In First Out
- 6 Prospective validation is performed on at least _____ successive batches.
 - a. Ten
 - b. Three
 - c. Five
 - d. Two

- 7 _____ is the key element responsible for the organizational growth and outcomes.
- Personnel
 - Equipment
 - Premises
 - Layout
- 8 Complaint investigation is the responsibility of _____.
- Quality Control department
 - Production department
 - Quality Assurance department
 - Marketing department
- 9 ISO 14001 is for _____ management.
- Quality
 - Environmental
 - Resource
 - Organization
- 10 Service bay is maintained at _____
- Class 1000
 - Class 20
 - Class 10
 - Class 50
- 11 Grammage is used to determine the physical dimensions of the _____ material.
- Thermosetting plastic
 - Metal
 - Glass
 - Paper and paperboard
- 12 A _____ container is closed by fusion of the material of the container.
- Sealed
 - Light- resistant
 - Hermetically sealed
 - Well closed
- 13 In _____ purchasing, different departments purchase their requirement separately.
- Closed
 - Centralized
 - Decentralized
 - Limited

- 14 Folding endurance is performed for _____
- Carton
 - Closure
 - Carton
 - Paperboard
- 15 Calibration of an equipment should be performed using _____.
- Test sample
 - Certified Standards
 - Inhouse standards
 - Reference sample
- 16 Which of the following is an example of secondary packaging?
- Bottles
 - Barrel
 - Blister
 - Cartons
- 17 In the test for volatile sulphides in rubber closure, _____ paper is used.
- Litmus paper
 - Lead acetate paper
 - Starch paper
 - Mercuric chloride
- 18 _____ is at the apex of Quality Management System.
- Quality Records
 - Quality procedures
 - Quality Manual
 - Working instructions
- 19 Cleaning of the equipment is a part of _____.
- Predictive maintenance
 - Corrective maintenance
 - Curative maintenance
 - Periodic maintenance
- 20 The vital link between all elements of TQM is _____
- Leadership
 - Communication
 - Training
 - Recognition

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

- 1 Define QbD. Elaborate on tools of QbD. Give the difference between QC and QA. **10**
- 2 Discuss quality control tests for plastic containers and rubber closure. **10**
- 3 Enlist the types of documents maintained in pharmaceutical company. Write in brief about master formula record. **10**

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

- 1 What is Quality management System? Give the role of Quality Control and Quality Assurance departments in a Pharmaceutical Industry **5**
- 2 Write in brief about disqualification of testing facilities. **5**
- 3 Define and differentiate between Quality audit and Quality Review. **5**
- 4 Enlist the benefits of ISO and explain the process of ISO registration. **5**
- 5 Discuss the training and personal records with reference to GMP in a pharmaceutical industry **5**
- 6 Define calibration. Elaborate on the process for calibration of the pH meter. **5**
- 7 Discuss the steps involved in handling of complaints in a pharmaceutical company. **5**
- 8 Explain the process of equipment selection and maintenance in the pharmaceutical manufacturing unit. **5**
- 9 State the importance of inventory management. Discuss the Good warehousing practices in detail. **5**
