

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 Which ICH guideline includes Risk management?
 - a. Q3
 - b. Q9
 - c. Q10
 - d. Q12
- 2 Following products cannot be manufactured in the same manufacturing facility
 - a. Antiviral product & Anti-inflammatory product
 - b. Antidiabetic & Antihypertensive product
 - c. Antimalarial product & Anti-inflammatory product
 - d. Penicillin products & Antidiabetic products
- 3 Which of the following does not belong to Juran's Quality Trilogy?
 - a. Quality Planning
 - b. Quality Assurance
 - c. Quality Control
 - d. Quality improvement
- 4 _____ 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
- 5 Cleaning of the equipment is a part of
 - a. Corrective maintenance
 - b. Predictive maintenance
 - c. Periodic maintenance
 - d. Curative maintenance
- 6 The acceptance criteria for wavelength accuracy in the visible range for calibration of spectrophotometer is _____
 - a. ± 1 nm
 - b. ± 2 nm
 - c. ± 3 nm
 - d. ± 5 nm

- 7 Installation qualification of an equipment verifies that ____.
- User requirements are incorporated into equipment design
 - Equipment operates consistently within operational limit
 - Equipment shows satisfactory performance over long period.
 - Equipment is installed and connected to utilities
- 8 Recall due to Microbial contamination of injection is an example of ____ recall
- Class I
 - Class II
 - Class III
 - Class IV
- 9 In “Quality by Design”, what does CQA stand for?
- Critical Quality Assessment
 - Critical Quality Attributes
 - Complex Quality Assessment
 - Complex Quality Attributes
- 10 Facility used for manufacturing of sterile products should be maintained at ____ differential pressure.
- Constant
 - Variable
 - Positive
 - Negative
- 11 As per USP, the limit of fragments visible to the naked eye in fragmentation test for rubber closures is _____.
- Not more than 50
 - Not more than 10
 - Not more than 5
 - Not more than 1
- 12 The OECD stands for _____.
- Organization for Environmental Control and Discussion
 - Organization for Economic Cooperation and Development
 - Organization for Environmental Cooperation and Development
 - Organization for Economic Control and Discussion
- 13 _____ is a process that demonstrates a particular instrument produces results within specified limits, as compared to those produced by a traceable standard.
- Validation
 - Qualification
 - Calibration
 - Verification

- 14 As per USFDA GLP guidelines, Subpart C is _____.
- Facilities
 - Equipment
 - Records and Reports
 - Test and Control Articles
- 15 Approval of release of finished product is the responsibility of _____.
- Head of Stores
 - Head of Quality Control
 - Head of Quality Assurance
 - Head of Production
- 16 _____ is the test in which test piece is folded back and forth until rupture occurs.
- Folding endurance
 - Tensile strength
 - Burst Resistance
 - Tear Strength
- 17 Records of a nonclinical study should be retained for _____ after termination / discontinuation of the study.
- One year
 - Two years
 - Three years
 - Five years
- 18 Type III glass is also known as _____.
- Soda lime glass
 - Borosilicate glass
 - Treated Soda lime glass
 - Treated borosilicate glass.
- 19 The efficiency of HEPA filters should be _____ at 0.22-micron particle size.
- 95.55%
 - 99.99%
 - 93.22%
 - 90.99%
- 20 Bracketing design for stability testing includes _____.
- Testing samples of all design factors at all time points
 - Testing samples of extreme design factors at all time points
 - Testing samples of all design factors at half time points
 - Testing samples of extreme design factors at half time points

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

- 1 Enlist the participants of ICH. Write in brief about photostability testing of drug products. 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 recall? Define Complaint and Discuss the steps involved in handling of complaints in a pharmaceutical company. 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 Discuss the QC tests for rubber closures. 5
- 3 Define SOP. Discuss the general format of SOP. 5
- 4 What is ISO? Discuss its benefits and the process of ISO registration. 5
- 5 Explain the process of equipment selection and maintenance in the pharmaceutical manufacturing unit. 5
- 6 State the importance of inventory management. Discuss the Good warehousing practices in detail. 5
- 7 Enlist the types of documents maintained in pharmaceutical company. Write in brief about batch formula record. 5
- 8 Write a note on maintenance of sterile areas. Illustrate a layout for manufacturing of injectables. 5
- 9 Define validation. Explain in brief the types of process validation. 5