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 ____.

a. User requirements are incorporated into equipment design
b. Equipment operates consistently within operational limit
c. Equipment shows satisfactory performance over long period.
d. Equipment is installed and connected to utilities

8 Recall due to Microbial contamination of injection is an example of _____ recall

a. Class I
b. Class II
c. Class III
d. Class IV

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

a. Critical Quality Assessment
b. Critical Quality Attributes
c. Complex Quality Assessment
d. Complex Quality Attributes

10 Facility used for manufacturing of sterile products should be maintained at _____ differential pressure.

a. Constant
b. Variable
c. Positive
d. Negative

11 As per USP, the limit of fragments visible to the naked eye in fragmentation test for rubber closures is _____.

a. Not more than 50
b. Not more than 10
c. Not more than 5
d. Not more than 1

12 The OECD stands for _____.

a. Organization for Environmental Control and Discussion
b. Organization for Economic Cooperation and Development
c. Organization for Environmental Cooperation and Development
d. 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.

a. Validation
b. Qualification
c. Calibration
d. Verification

14 As per USFDA GLP guidelines, Subpart C is _____.
   a. Facilities
   b. Equipment
   c. Records and Reports
   d. Test and Control Articles

15 Approval of release of finished product is the responsibility of ____.
   a. Head of Stores
   b. Head of Quality Control
   c. Head of Quality Assurance
   d. Head of Production

16 _____ is the test in which test piece is folded back and forth until rupture occurs.
   a. Folding endurance
   b. Tensile strength
   c. Burst Resistance
   d. Tear Strength

17 Records of a nonclinical study should be retained for _____ after termination / discontinuation of the study.
   a. One year
   b. Two years
   c. Three years
   d. Five years

18 Type III glass is also known as _____.
   a. Soda lime glass
   b. Borosilicate glass
   c. Treated Soda lime glass
   d. Treated borosilicate glass.

19 The efficiency of HEPA filters should be _____at 0.22-micron particle size.
   a. 95.55%
   b. 99.99%
   c. 93.22%
   d. 90.99%

20 Bracketing design for stability testing includes _____.
   a. Testing samples of all design factors at all time points
   b. Testing samples of extreme design factors at all time points
   c. Testing samples of all design factors at half time points
   d. 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**