QA
6 attt
23/10/24

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 Lifecycle Management falls under which ICH guideline?

a. Q3
b. Q9
c. Q10
d. Q12

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

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

3 The vital link between all elements of TQM is_____

a. Leadership
b. Communication
c. Recognition
d. Training

4 Water attack test is performed on _____ glass

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

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. Drug and Cosmetic Act
d. Companies Act

6 Prospective validation is performed on at least _____ successive batches.

a. Seven
b. Three
c. Five
d. Ten

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7 The following is verified during operational qualification of an equipment.
   a. Equipment is installed and calibrated
   b. Equipment operates consistently within operational limit
   c. Equipment shows satisfactory performance over long period.
   d. Equipment is installed and connected to utilities

8 Complaint investigation is the responsibility of _____.
   a. Marketing department
   b. Quality Assurance department
   c. Quality Control department
   d. Production department

9 Quality by Design" is associated with which of these following ICH guidelines?
   a. Development & Manufacture of Drug substance
   b. Analytical Procedure Development
   c. Pharmaceutical Development
   d. Specifications

10 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

11 Cobb test measures the ____ of paper and board
   a. Ink absorbency
   b. Water absorbency
   c. Acid absorbency
   d. Alkali absorbency

12 The principles of GLP applies to _____.
   a. Conduct of clinical studies
   b. Conduct of nonclinical studies
   c. Conduct of analytical studies
   d. Conduct of microbiological studies

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

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14 As per USFDA GLP guidelines, Subpart F is _____.

a. Facilities
b. Equipment
c. Records and Reports
d. Test and Control Articles

15 Room classification tests in the "at-rest" condition should be carried out _____.

a. With the equipment installed, HVAC operational, but without any operators
b. In the empty room, in the absence of any equipment or personnel
c. During the normal production process with equipment operating under normal conditions.
d. With the normal number of personnel present in the room.

16 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

17 Self-sealability test is intended for _____.

a. Rubber closures of single dose container
b. Rubber closures of multi dose containers
c. Plastic closures of single dose containers
d. Plastic closures of multidose containers

18 Corrections to the final report by study director are in the form of _____

a. Revised edition
b. Oral communication
c. Amendment
d. Revised Version

19 The efficiency of HEPA filters should be _____at 0.22micron 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

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Q. II	**Answer any two questions. (Any 2)**	**20**
1	Elaborate on stability guidelines for new drug substances.	10
2	Define GLP. Write in brief about disqualification of testing facility.	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	Define QbD. Elaborate on tools of Qbd.	5
2	Discuss the quality control tests for plastic containers. Enlist the tests, procedure for each test with limit	5
3	Discuss Quality Review and Quality documentation in pharmaceutical industry.	5
4	What is NABL accreditation and its benefits? Discuss its process.	5
5	Explain in detail the equipment selection and maintenance of stores for raw materials	5
6	Enlist the types of process validation. Explain the process for calibration of pH meter.	5
7	Discuss "Quality audit" in pharmaceutical industry.	5
8	Write a note on utilities and maintenance of sterile areas. Illustrate a layout of Tablet manufacturing unit.	5
9	Define Validation. Give the process for qualification of UV-visible spectrophotometer.	5

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