Duration: 3 hours **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 MedDRA terminology guideline is a part of _____ guidelines.
- a. Quality
- b. Safety
- c. Efficacy
- d. Multidisciplinary

2 Airlock doors should be equipped with systems that_____.
- a. Prevent simultaneous opening of both the doors
- b. Allow simultaneous opening of both the doors
- c. Prevent simultaneous opening of doors by unauthorized persons
- d. Allow simultaneous opening of both the doors by authorized persons

3 The aim of _____ is to identify the defects in the finished products.
- a. Quality Assurance
- b. Quality Control
- c. GMP
- d. Production

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

5 The premises/building used for manufacturing shall conform to all the conditions laid down in _____.
- a. Pharmacy Act
- b. Factories Act
- c. Environment Act
- d. Industrial Relation Act

6 The ____ of an analytical procedure is the interval between the lowest and the highest reportable results.
- a. Accuracy
- b. Range
- c. Precision
- d. Repeatability

7 Cleaning of the equipment is a part of _____.

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

8 Which is the second step in Handling of complaints?

a. Monthly trend analysis
b. Corrective action
c. Technical investigation
d. Receiving of complaints

9 Which of the following is known as a binding mortar of TQM?

a. Ethics
b. Communication
c. Trust
d. Recognition

10 The integrity of HEPA filter should be checked _____.

a. Daily
b. Weekly
c. Monthly
d. Yearly

11 The_____is responsible for the conduct of a nonclinical laboratory study.

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

12 Tear strength measures the_____.

a. Energy required to make puncture in the paper
b. Force that a paper withstands before breaking
c. Degree of resistance offered by paper when it is folded
d. Force required to tear an initial cut in the paper

13 In the pharmaceutical industry, FEFO is ____.

a. First Expired First Out
b. First Exit First Out
c. First Ended First Out
d. First Evaluated First Out

14 Type III glass is also known as_____.

a. Soda lime glass
b. Borosilicate glass
c. Treated Soda lime glass
d. Treated borosilicate glass

15 During design qualification of an equipment, the following is required

a. User Requirement Specification
b. Standard Operating Procedure
c. Operating Manual
d. Maintenance report

16 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

17 _____ test is specifically used for testing glass containers used for aqueous parenterals.

a. Light transmission test
b. Arsenic test
c. Thermal Shock test
d. Internal bursting pressure test

18 The SOPs are reviewed after_____.

a. One year
b. Two years
c. Three years
d. Five years

19 A job description is an organized factual statement of the _____ of a specific job.

a. Report
b. Policy
c. Schedule
d. Responsibilities

20 CPP stands for _____.

a. Critical Product Parameter
b. Critical Product Process
c. Critical Process Parameter
d. Critical Product Profile

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

1	Define ICH. Enlist ICH Q series guidelines. Explain the process of harmonization.	**10**
2	Define GLP. Discuss in brief the protocol for conduct of nonclinical study.	**10**
3	Enlist the types of documents maintained in pharmaceutical company. Write in brief about batch formula record.	**10**

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

1	Explain the NABL accreditation procedure for a testing laboratory	**5**
2	Discuss the Quality Control tests for rubber closures	**5**
3	What is recall and returned product? Write in brief about handling of complaints.	**5**
4	What is ISO? Explain the benefits and elements of ISO 9000.	**5**
5	Write a note on selection of equipment and its maintenance.	**5**
6	Define validation. Discuss in detail about types of process validation.	**5**
7	State the purpose of distribution records. Write a note on Master FormulaRecord**.**	**5**
8	Enlist Key Personnel. Describe the responsibilities of Head of Production	**5**
9	Describe the concept of material management.	**5**

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