(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 ICH Q 8 represents _____ guidelines. **01**
a. Quality Risk Management
b. Good Manufacturing Practices
c. Lifecycle management
d. Pharmaceutical Development

2 Airlock doors should be equipped with systems that_____. **01**
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 Following are tools of QbD except__. **01**
a. Critical Quality Attributes
b. Process Analytical Technology
c. Risk assessment
d. Design of Experiments

4 As per USFDA GLP guidelines, Subpart C is_____. **01**
a. Equipment
b. Facilities
c. Records and Reports
d. Organization and personnel

5 Personal records are records of_____in an organization. **01**
a. Employer
b. Employees
c. Visitors
d. Auditors

6 Retrospective validation is performed using data from minimum ____ consecutive batches **01**
a. One
b. Three
c. Five
d. Ten

7 Cleaning of the equipment is a part of_____. **01**
a. Periodic maintenance
b. Predictive maintenance
c. Corrective maintenance
d. Curative maintenance

8 The SOP's are reviewed after_. **01**
a. One year
b. Two years
c. Three years
d. Five years

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9 The validity of NABL accreditation is for___. **01**
- a. Six months
- b. One year
- c. Two years
- d. Three years

10 Air pressure differentials in a clean room should be checked_____. **01**
- a. Daily
- b. Yearly
- c. Biannually
- d. Weekly

11 Self sealability test is intended for___.
- a. Rubber closures of single dose container **01**
- b. Rubber closures of multi dose containers
- c. Plastic closures of single dose containers
- d. Plastic closures of multidose containers

12 Minimum number of glass containers of 3 ml nominal capacity used for hydrolytic resistance test are_____. **01**
- a. 20
- b. 10
- c. 05
- d. 02

13 _____is carried out in connection with the introduction of new drug products. **01**
- a. Retrospective validation
- b. Prospective validation
- c. Concurrent validation
- d. Revalidation

14 Grammage is used to determine the physical dimensions of the____material. **01**
- a. Paper and paperboard
- b. Thermosetting plastic
- c. Glass
- d. Metal

15 The efficiency of HEPA filters should be___at 0.22micron particle size. **01**
- a. 95.55%
- b. 99.99%
- c. 93.22%
- d. 90.99%

16 Cobb test measures the_____of paper and board **01**
- a. Ink absorbency
- b. Water absorbency
- c. Acid absorbency
- d. Alkali absorbency

17 Neutral glass is also called as _____. **01**
- a. Type I glass
- b. Type II glass
- c. Type III glass
- d. NP glass

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18 Which is the second step in Handling of complaints? **01**
   a. Monthly trend analysis
   b. Corrective action
   c. Technical investigation
   d. Receiving of complaints

19 The highest air pressure is maintained in_____. **01**
   a. Clean Room
   b. Gowning room
   c. Factory Hallway
   d. Store room

20 _____is a managerial tool. **01**
   a. Quality Control
   b. Quality Assurance
   c. Production
   d. Accreditation

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

1 Define QbD. Write a note on tools of QbD. Explain the benefits and process of ISO 9000 registration. **10**

2 Define GLP. Discuss in brief the protocol for conduct of nonclinical study. **10**

3 Write a note on handling of returned goods. Discuss the disposal of waste in pharmaceutical industry **10**

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

1 Enlist the ICH Q series guideline titles. Write in brief about Stability testing of new drug substances. **5**

2 Enlist the quality control tests for glass containers. Discuss in brief the hydrolytic resistance test. **5**

3 Discuss Quality Review and Quality documentation in pharmaceutical industry. **5**

4 What is Quality management system? Give the difference between QA & QC. **5**

5 Write in brief about personal training. Discuss the responsibilities of key personnel. **5**

6 Define validation. Explain in brief the types of process validation. **5**

7 What is recall? Explain in detail the process for handling of complaints. **5**

8 Discuss the process of equipment selection and its maintenance. **5**

9 Enlist the types of process validation. Explain the process for calibration of pH meter. **5**

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