Seat No: _____ Enrollment No: _____

PARUL UNIVERSITY

FACULTY OF PHARMACY

B. Pharm. Summer 2022-23 Examination

Semester: 6 **Date: 26/04/2023**
Subject Code: BP606T **Time: 10:00am to 1:00pm**
Subject Name: Quality Assurance **Total Marks: 75**

Instructions:
1. Figures to the right indicate maximum marks.
2. Make suitable assumptions wherever necessary.

Q.1 Multiple Choice Questions (MCQs) (1 Mark Each) **(20)**

1. The objective of ISO-9000 family is
   a) Customer satisfaction b) Employee satisfaction
   c) Skill enhancement d) Environmental issues
2. Which of the following is not a tool of QbD?
   a) Design of Experiment b) Risk assessment
   c) Process Analytical Technology d) Quality targeted product profile
3. Stability Data for Climatic zone III & IV comes under _____ICH guidelines.
   a) Q1C b) Q1D
   c) Q1E d) Q1F
4. Which Guideline has to be followed for Analytical procedure development ?
   a) Q14 b) Q3
   c) Q2 d) Q4
5. The size of airborne particles that serves as a parameter for environmental monitoring and classification of clean rooms include
   a) ≥0.5 μm and ≥ 5.0 μm b) ≥0.10 μm and ≥15.0 μm
   c) ≥0.87 μm and ≥50.0 μm d) ≥1 μm and ≥15.0 μm
6. To approve or reject starting, packaging material is a responsibility of
   a) Head of QC department b) Head of Production department
   c) Head of QA department d) Head of Packaging department
7. Adequate space should be provided for logical and orderly placement of _____
   a) Raw materials b) Equipments
   c) Packaging Materials d) Spare parts
8. Materials used for construction of equipment should be non reactive with
   a) Raw material b) API
   c) Products d) All of the above
9. For ampoules Container/Closure integrity test which of the following solution is employed?
   a) 1%scarlet green b) 1%erythrosin
   c) 1% methylene blue d) all of these
10. Which of the following is the test to check the Chemical resistance of glass containers?
    a) Arsenic test b) Thermal resistance test
    c) Powdered glass test d) Leakage test
11. In GLP, it is prescribed that study director should be a ____
    a) Doctor b) Pharmacist
    c) Scientist d) None of these
12. The principles of GLP suggested by OECD in which year?
    a) 1978 b) 1980
    c) 1981 d) 1990
13. The primary documentation to be reviewed in technical investigation stage of complaint handling involves
    a) Complaint files and the batch records b) Name, address, phone number and email of customer
    c) Complaint sample d) Reserve samples

14. An audit performed by an organization on itself is
    a) Internal audit
    b) Second party audit
    c) A third party audit
    d) None of the above
15. A written data related to distribution of drug products from the manufacturer to the distributor is a
    a) Distribution record
    b) Validation protocols and reports
    c) Technical transfer reports
    d) Audit plans
16. Written records involving a drug product shall be maintained for at least _____year from the expiration date of the drug product.
    a)One
    b) Five
    c)Three
    d)Ten
17. Physical dimension of equipment and accessories-comes under which qualification?
    a) Design Qualification
    b) Installation Qualification
    c) Operational Qualification
    d) Performance qualification
18. Which reagent is used to check control of absorbance in calibration of UV spectrophotometer?
    a) Potassium dichromate solution
    b) Toluene in hexane
    c) Potassium chloride
    d) Sulphuric acid
19. If product has to be formulated with higher dose, it will undergo:
    a) Prospective validation
    b) Retrospective validation
    c) Revalidation
    d) Concurrent validation
20. The degree of closeness amongst all agreements called as____
    a) Range
    b) Linearity
    c) Accuracy
    d) Precision

Q.2 Long Answers (any 2 out of 3) (10 Mark Each) **(20)**

1. Discuss ICH QSEM guidelines. Explain ICH stability Guideline in detail.
2. Discuss responsibility of key personnel in Pharmaceutical industry and study director & QA person in GLP.
3. Write a note on MFR. Explain in detail Analytical method validation.

Q.3 Short Answers (any 7 out of 9) (5 Mark Each) **(35)**

1. What is QbD? Discuss Elements of QbD.
2. Discuss utilities and maintenance of sterile area.
3. Explain maintenance and purchase specification of Equipments.
4. Expalin Quality control test for conatiners.
5. Write in detail about protocol for Conduct of a nonclinical Laboratory Study.
6. Explain about Quality audit, Quality Review and Quality documentation.
7. Write a note on complaints and Evaluation of complaints.
8. Write in detail about Good warehousing practice.
9. Define calibration and Qualification. Explain Qualification of Equipments.