

**B. PHARM.
SIXTH SEMESTER
QUALITY ASSURANCE
BP606T**

**SET
C**

[USE OMR SHEET FOR OBJECTIVE PART]

Duration : 3 hrs.

Full Marks : 75

(PART-A: Objective)

Time : 30 min.

Marks : 20

Choose the correct answer from the following:

1×20=20

- The format of Validation Master Plan should include:
 - Documentation format
 - Key acceptance criteria
 - Both a and b
 - None of these
- _____ are the specifications a manufacturer uses to describe a device or equipment.
 - Installation qualification
 - Design qualification
 - Performance qualification
 - Operational qualification
- SOP should be written in:
 - active voice, present tense
 - active voice, past tense
 - passive voice, present tense
 - None of these
- What is the full form of OECD?
 - Organization for Economic Control & Drugs
 - Organization for Excise Control & Duty
 - Organization for Economic Cooperation & Development
 - None of the above
- Incineration method refers to a:
 - Sterilization method
 - Waste disposal method
 - Both a and b
 - None of these
- E. For chemical disinfection which compounds are used?
 - Chlorine compounds
 - Phenol compounds
 - Both a and b
 - None of these
- The self-sealability test is an important test performed for closures of which type of products?
 - All parenteral
 - Single-dose parenteral
 - Multi-dose parenteral
 - All of these
- GMP consists of how many components?
 - 5
 - 6
 - 4
 - 3
- GLP is designated as a new part of Chapter 21 of the CFR as:
 - 21 CFR Part 58
 - 21 CFR Part 56
 - 22 CFR Part 58
 - 22 CFR Part 56

10. Communal wastes include:
 - a. Cardboard
 - b. Tissue
 - c. Needles
 - d. None of these
11. GLP is a formal regulation created by USFDA and these regulations were proposed on:
 - a. Nov 20, 1978
 - b. Nov 19, 1976
 - c. Nov 22, 1976
 - d. Nov 21, 1978
12. _____ is also referred to as Self-Audit.
 - a. Internal Audit
 - b. External Audit
 - c. Regulatory Audit
 - d. All of the above
13. The arsenic test is conducted for glass containers intended for what purpose?
 - a. All aqueous products
 - b. Oral dosage forms
 - c. Aqueous parenteral products
 - d. None of these
14. The water attack test is used for which type of glass?
 - a. Type I
 - b. Type II
 - c. Both a and b
 - d. None of these
15. In powdered glass test which indicator is used?
 - a. Phenolphthalein
 - b. Methyl orange
 - c. Methyl red
 - d. None of these
16. The 'S' in QSEM stands for:
 - a. Stability
 - b. Safety
 - c. Sanitization
 - d. None of these
17. QA is a _____ tool.
 - a. managerial
 - b. Corrective
 - c. safety
 - d. None of these
18. QC is _____ oriented.
 - a. process
 - b. product
 - c. provision
 - d. performance
19. The Q₇ guidelines describes about:
 - a. Quality risk management
 - b. Pharmacopoeia
 - c. GMP
 - d. Impurities
20. The long term testing conditions for temperate zones is:
 - a. 25°C, 60% RH
 - b. 21°C, 45% RH
 - c. 30°C, 45% RH
 - d. None of these

(PART-B : Descriptive)

Time : 2 hrs. 30 min.

Marks : 35

[Answer any seven (7) questions]

1. Describe about the design and construction of Premises. 5
2. Explain about the objectives and elements of TQM. 5
3. Explain the various tests for plastic containers. 5
4. Mention the various steps for handling and evaluation of complaints. 5
5. Write short notes on the following: 5
SOPs
Quality Audits
6. Explain the various tests for paper and boards as secondary packaging materials. 5
7. Describe about the ICH guidelines. 5
8. Write a detailed note on Plant Layout. 5
9. What are the various measures taken in industries for the control of contamination? 5

(PART-C: Long type questions)

[Answer any two (2) questions]

1. Write a detailed note on the various categories of GMP. 10
2. Describe the various GLP Practices. 10
3. Write in details about the handling of waste materials and their disposal in the pharmaceutical industries. 10