

B. PHARM
SIXTH SEMESTER
QUALITY ASSURANCE
BP606T

(USE SEPARATE ANSWER SCRIPTS FOR OBJECTIVE & DESCRIPTIVE)

Duration: 3 hrs.

Full Marks: 75

[PART-A: Objective]

Time: 20 min.

Marks: 20

Choose the correct answer from the following:

1×20=20

1. The ICH guidelines are mainly divided into QSEM where S represents?
 - a. Safety
 - b. Stability
 - c. Sterility
 - d. All of them
2. _____ is a system of continuous improvement employing participative management and centred on the needs of customers.
 - a. Quality Control
 - b. Quality assurance
 - c. TQM
 - d. None of the above
3. The ICH secretariat is based in
 - a. Geneva
 - b. Europe
 - c. United States
 - d. Japan
4. Assessment of validity or action of proving effectiveness is-
 - a. Validation
 - b. Discarded drug
 - c. Chemo waste
 - d. All of these
5. _____ is one of the primary processes used to maintain instrument accuracy?
 - a. Calibration
 - b. Validation
 - c. Sterility
 - d. All of them
6. Major complaints are comes under which type?
 - a. A type
 - b. B type
 - c. C type
 - d. None of the above
7. Q8 guideline for
 - a. Pharmaceutical product development
 - b. Analytical method validation
 - c. Pharmacopoeias
 - d. Stability studies
8. Q7 guideline for
 - a. Good manufacturing practices
 - b. Analytical method validation
 - c. Pharmacopoeias
 - d. Stability studies
9. ISO 9000 is a series of _____ standards.
 - a. Quality Control
 - b. Environmental management
 - c. Quality management
 - d. None of the above
10. ISO 14000 is a series of _____ standards.
 - a. Environmental management
 - b. Organizational management
 - c. Quality management
 - d. None of the above

11. Organizational requirements for achieving a successful quality system include
- a. Leadership
 - b. Planning process
 - c. Monitoring
 - d. All of these
12. In _____ all the machines are arranged in the sequence, as required to produce a specified product.
- a. Product Layout
 - b. Line layout
 - c. Both a and b
 - d. None of these
13. _____ Maintenance is the type of planned maintenance.
- a. Preventive
 - b. Corrective
 - c. Predictive
 - d. All of these
14. Presence of waste heat in the water causes
- a. Thermal pollution
 - b. Heat pollution
 - c. Water pollution
 - d. None of these
15. _____ maintenance is an emergency based policy in which the plant or equipment is operated until it fails.
- a. Breakdown
 - b. Corrective
 - c. Shutdown
 - d. None of these
16. Packing which is in direct contact with the product itself is called
- a. Secondary
 - b. Tertiary
 - c. Primary
 - d. All of these
17. Carton is a type of _____ packaging.
- a. Primary
 - b. Tertiary
 - c. Secondary
 - d. None of these
18. _____ is a quality control test for glass container.
- a. Powdered glass test
 - b. Hydrolytic resistance of glass container
 - c. Thermal shock test
 - d. All of these
19. _____ comes under the category of return goods.
- a. Date expired goods
 - b. Broken seal
 - c. Product unidentifiable
 - d. All of these
20. _____ is a pharmaceutical waste.
- a. Expired drug
 - b. Discarded drug
 - c. Chemo waste
 - d. All of these

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(PART-B : Descriptive)

Time: 1 hr. 40 minutes

Marks : 35

[*Answer any seven (7)*]

1. Write different functions of QA. 5
2. Write different functions of QC. 5
3. Write different objectives of TQM. 5
4. Write different types of complaints. 5
5. What is calibration? Discuss calibration of pH meter. 5
6. Discuss for pharmaceutical product recall. 5
7. Write objectives of market complaints 5
8. Discuss the types of environmental pollution. 5
9. Discuss principle of plant layout. 5

Time : 1 Hr.

Marks : 20

[*Answer any two (2)*]

1. What is contamination? What are the types of contaminant? Discuss control of contamination of peoples. 10
2. What is validation? Write a note on importance of Validation. 10
3. Write a note on ICH quality guideline. 10

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