

B. PHARM.
SIXTH SEMESTER
PHARMACEUTICAL QUALITY ASSURANCE
BP606T[SPECIAL REPEAT]
[USE OMR SHEET FOR OBJECTIVE PART]

SET
A

Duration: 3 hrs.

Full Marks: 75

Time: 30 min.

(PART-A: OBJECTIVE)

Marks: 20

Choose the correct answer from the following:

1×20=20

1. A situation in which the use of, or exposure to, a defective product is not likely to cause any adverse health consequences.
 - a. Class 1 recall drug
 - b. Class 2 recall drug
 - c. Class 3 recall drug
 - d. None of the above
2. The waste generated during treatment or diagnosis of human beings or animals, during biological material production and testing.
 - a. Biomedical waste
 - b. Medical waste
 - c. Hazardous waste
 - d. Non- hazardous waste
3. A written approval documents for each batch of the product being processed, in which data has been filled in during processing of the batch.
 - a. Good manufacturing records
 - b. Batch manufacturing record
 - c. Standard operating records
 - d. Master formula record
4. The ability to assess unequivocally, an analyte, in the presence of other components that are expected to be present".
 - a. Precision
 - b. Linearity
 - c. Robustness
 - d. Specificity
5. The document that provides information about the company's validation programme
 - a. Validation master plan
 - b. Design qualification
 - c. Revalidation
 - d. Operational qualification
6. Water attack test is only perform for _____
 - a. Type I glass
 - b. Type II glass
 - c. Type III glass
 - d. Type IV glass
7. The mean force required to continue the tearing of an initial cut in a single sheet of paper.
 - a. Burst strength
 - b. Grammage
 - c. Tensile strength
 - d. Folding endurance
8. Any changes in an approved protocol must be documented along with the reasons and signed by
 - a. Management
 - b. Sponsors
 - c. Quality assurance unit
 - d. Study director

9. The test for closures intended for multiple dosage use is_____
 - a. Fragmentation test
 - b. Self-sealability test
 - c. Sterilization test
 - d. Leakage test
10. The American glass research increment pressure tester is a common instrument used for
 - a. Internal bursting test
 - b. Collapsibility test
 - c. Thermal shock test
 - d. Water attack test
11. Physical dimension of equipment and accessories come under which qualification?
 - a. Design qualification
 - b. Installation qualification
 - c. Operational qualification
 - d. Performance qualification
12. The filling of products for terminal sterilization should generally be done in at least which environment?
 - a. Grade A
 - b. Grade B
 - c. Grade C
 - d. Grade D
13. The efficiency of HEPA filters should be.....at 0.22micron particle size
 - a. 95.55%
 - b. 99.99%
 - c. 93.22%
 - d. 90.99%
14. The building used for the manufacture of drugs should conform to all the condition laid down in.....
 - a. Pharmacy Act
 - b. Factories Act
 - c. Drug and Cosmetics Act
 - d. Companies Act
15. Approval of release of finished product is the responsibility of.....
 - a. Head of stores
 - b. Head of Quality Control
 - c. Head of Quality Assurance
 - d. Head of Production
16. Cleaning of the equipment is a part of.....
 - a. Periodic maintenance
 - b. Predictive
 - c. Corrective
 - d. Curative
17. In which year ISO was born?
 - a. 1945
 - b. 1955
 - c. 1947
 - d. 1960
18. Who was the first to develop the concept of QbD?
 - a. Dr. Joseph M'juran
 - b. W.Edward Deming
 - c. Walter A.Shewhat
 - d. Frederick W. Taylor
19. Total quality management focuses on.....
 - a. Customer
 - b. Employee
 - c. Both A&B
 - d. None of the above
20. ICH Q10 guidelines refer to
 - a. Pharmaceutical quality
 - b. Pharmaceutical product lifestyle
 - c. Development and manufacture
 - d. Stability testing

(PART-B :Descriptive)

Time : 2 hrs. 30 min.

Marks : 35

[Answer any seven (7) questions]

1. Define validation? Explain the different types of validation? 5
2. Define validation master plan? Write the contents of validation master plan? 1+4=5
3. Explain the protocol for and conduct of non-clinical laboratory study? 1+4=5
4. Write in brief about the Q-series guidelines. 5
5. Explain the different methods of disposal of pharmaceutical waste? 5
6. Write down the maintenance of sterile area. 5
7. Differentiate between QA and QC 5
8. Write a note on QTPP and CQAs. 5
9. Briefly explain about batch manufacturing records and its contents? Write 5

PART-C: Long type questions

[Answer any two (2) questions]

1. Write down the role of QA in pharma industries 4+3+3
=10
2. Write down the aim of ISO and briefly explain about ISO 9000 family 5+5=10
3. Enlist the type of glass containers used in pharmaceutical industry? Explain powdered glass test and water attack test? 10

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