**SET A**

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

[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***

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 0.22 micron 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

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## PART-B :Descriptive

**Time : 2 hrs. 30 min.** **Marks : 35**

*[ Answer any seven (7) questions ]*

1. Explain the protocol for and conduct of non-clinical laboratory study? 5

2. Define validation master plan? Write the contents of validation master plan? 1+4=5

3. Define validation? Explain the different types of validation? 1+4=5

4. Briefly explain about batch manufacturing records and its contents? 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

8. Write in brief about the Q series guidelines. 5

9. Write a note on QTPP and CQAs. 5

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## PART-C: Long type questions

*[ Answer any two (2) questions ]*

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

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