

BP606T- QUALITY ASSURANCE

Detail answers (10m)

1. What is good warehousing practices? Describe briefly material management in a warehouse.
2. Compare calibration, qualification and validation. How do you prepare validation master plan? Describe calibration of UV-visible spectrophotometer.
3. What are the general principles of analytical method development? Compare accuracy and precision of LOD and LOQ with reference to ICH guidelines.
4. (a) Explain the importance and types of validation.
(b) Give the general principles of analytical method validation
5. Write the qualification of UV-Visible spectrophotometer.

Write notes (5m)

1. General principles of analytical method validation.
2. Compare calibration, qualification and validation.
3. Good warehousing practice.
4. Write a note on validation master plan.
5. Discuss the calibration of pH meter.
6. Signification of equipment validation.
7. Qualification of UV – Visible spectrophotometer.

Short answers (2m)

1. Validation master plan.
2. Good warehousing practice.
3. Materials management.
4. Calibration of pH meter.
5. Calibration
6. Types of validation.
7. User requirement specification.
8. Factory acceptance test.
9. Process validation.
10. Precision
11. LOD
12. LOQ
13. Validation
14. Qualification
15. Accuracy
16. Cleaning validation
17. Revalidation