unit 5 QUESTION

Unit V Syllabus Topics

- Calibration and Validation: Introduction, definitions, general principles, importance, scope, types, validation master plan, calibration of pH meter, qualification of UV-Visible spectrophotometer, analytical method validation.
- Warehousing: Good warehousing practice, materials management.

Possible 2-Mark Questions

1. Define calibration.
2. What is validation in the pharmaceutical industry?
3. Name two types of validation.
4. What is a validation master plan?
5. State the purpose of calibrating a pH meter.
6. What is qualification of equipment?
7. Define analytical method validation.
8. What is meant by good warehousing practice?
9. Mention one aspect of materials management in warehousing.
10. Give one example of equipment qualification.

Possible 5-Mark Questions

1. Explain the general principles of calibration.

2. Discuss the importance and scope of validation in pharmaceuticals.
3. Write a short note on the types of validation.
4. Describe the steps involved in the calibration of a pH meter.
5. What is a validation master plan? Outline its key components.
6. Explain the process of qualification of a UV-Visible spectrophotometer.
7. Write a note on general principles of analytical method validation.
8. Describe good warehousing practices in the pharmaceutical industry.
9. Explain the main elements of materials management in warehousing.
10. Discuss the significance of equipment qualification in quality assurance.

Possible 10-Mark Questions

1. Describe in detail the process of calibration and validation, including their definitions, principles, importance, types, and examples from the pharmaceutical industry.
2. Explain the various types of validation, the structure and purpose of a validation master plan, and how these contribute to product quality.
3. Discuss the procedures and importance of calibration of pH meters and qualification of UV-Visible spectrophotometer in pharmaceutical analysis.
4. Write an essay on analytical method validation, covering its general principles, steps, and significance in pharmaceutical quality control.
5. Explain good warehousing practices and materials management in the pharmaceutical industry, highlighting their role in ensuring product quality and regulatory compliance.