



BP606T- QUALITY ASSURANCE

Detail answers (10m)

1. What is the concept of TQM, describe in details various elements required for management of quality in pharmaceutical industry.
2. Discuss the concept Quality by design. What are various elements and tools required for the same?
3. (a) Describe the process of harmonization of ICH guidelines. (b) Explain the ICH stability testing guidelines.
4. Discuss the principles and procedures involved in NABL accreditation.
5. Write a note on concepts and philosophy of GMP.

Write notes (5m)

1. Explain the principles and procedures involved in NABL accreditation.
2. Write a note on ICH stability testing guidelines.
3. Explain the elements of quality by design program.
4. Write at least ten elements or criteria are followed in the ISO 9000 series standards.
5. Elements and philosophies of total quality management.
6. What are the steps for the registration of ISO 9000?
7. Brief overview of QSEM.
8. Benefits and elements of ISO 9000 and ISO 14000.
9. Write details on GMP with respect to sanitation and hygiene.
10. QSEM with special emphasis on Q-series guidelines.
11. Compare the concept of QA and QC as per GMP.

Short answers (2m)

1. Quality control.
2. Quality assurance
3. ISO 14000
4. Tools and elements of Qbd.
5. Principles of NABL Accreditation.

6. Purpose of ICH guidelines.
7. Concept of GMP.
8. Q-series guidelines.
9. Quality managements.
- 10.Elements of TQM.
- 11.ISO 9000
- 12.Total quality management.
- 13.Quality by design tools.
- 14.ICH.
- 15.cGMP.