2 marks and 5 marks 10 marks for unit 1

Possible 2-Mark Questions (Short Answer)

1. Define Quality Control.
2. Define Quality Assurance.
3. What is GMP?
4. What is Total Quality Management (TQM)?
5. Name any two elements of TQM.
6. What is the main objective of ICH guidelines?
7. Who are the main participants in ICH?
8. Expand QSEM in the context of ICH guidelines.
9. What is QbD?
10. Name any two tools used in QbD.
11. What are ISO 9000 standards?
12. What is the main benefit of ISO 14000 certification?
13. What does NABL stand for?
14. State one principle of NABL accreditation.
15. What is the purpose of ICH stability testing guidelines?

Possible 5-Mark Questions (Short Note/Brief Answer)

1. Write a short note on the concept and importance of Quality Assurance in the pharmaceutical industry.
2. Explain the elements and philosophies of Total Quality Management (TQM).
3. Describe the process of harmonization in ICH.
4. Write a brief overview of the Q-series guidelines of ICH.
5. Discuss the elements and benefits of ISO 9000 standards.

6. Write a note on the steps for ISO 14000 registration.
7. Explain the overview and elements of a Quality by Design (QbD) program.
8. Describe the principles and procedures of NABL accreditation.
9. What is the significance of ICH stability testing guidelines?
10. Write a short note on the benefits of implementing TQM in pharmaceutical industries.

Possible 10-Mark Questions (Long Answer/Essay Type)

1. Explain in detail the concepts of Quality Control, Quality Assurance, and GMP. How do they interrelate in pharmaceutical industries?
2. Discuss the definition, elements, and philosophies of Total Quality Management (TQM). How is TQM implemented in the pharmaceutical industry?
3. Describe the ICH guidelines in detail, including their purpose, participants, process of harmonization, and a brief overview of the Q-series guidelines.
4. Explain the concept of Quality by Design (QbD), its elements, and the tools used in QbD. How does QbD improve pharmaceutical product development?
5. Discuss the ISO 9000 and ISO 14000 standards: their overview, benefits, elements, and the steps required for registration in pharmaceutical industries.
6. Explain the principles and procedures of NABL accreditation. Why is it important for pharmaceutical laboratories?
7. Compare and contrast ISO 9000 and ISO 14000 standards in the context of pharmaceutical quality management.
8. Discuss the significance of ICH stability testing guidelines and their impact on global pharmaceutical quality assurance.

Tips for Answering

- For **2-mark questions**, provide concise definitions or direct answers.
- For **5-mark questions**, write a brief explanation with key points or steps.

- For **10-mark questions**, structure your answer with an introduction, detailed explanation, examples, and a conclusion.