

UNIT-IV: Quality Management Systems

Elaborate Questions (10 Marks):

1. Discuss **Total Quality Management (TQM)** and its importance in pharmaceutical industries [4, 5, 11].
2. Explain the concept of **Quality by Design (QbD)**. Discuss its elements and tools in pharmaceutical product development [4, 5, 10].

Notes Questions (5 Marks):

1. Explain in brief the concept of **Quality by Design (QbD)** [4, 5, 8, 10].
2. Write a note on the **Six Sigma concept** [4, 8, 13, 15].
3. Discuss **Total Quality Management** [4, 5, 11].
4. Briefly describe **Quality Risk Management** and give its principle [4, 8, 13].
5. What are the **ISO 9000 series of quality standards?** [4, 9]
6. Explain **ISO 14000** [4, 11].
7. Write a note on **Good Laboratory Practices (GLP)** [4, 10].

Short Answer Questions (2 Marks):

1. What is **quality control?** [15]
2. What is **Good Manufacturing Practices (GMP)?** [15]
3. Define **Six Sigma** [15].
4. What is the **Six Sigma Concept?** [13, 16]
5. Define **Quality by Design (QbD)** [8, 10].
6. Define **Quality Risk Management** and give its principle [8, 13].
7. What is **NABL certification?** [13]