

QUALITY ASSURANCE 6TH SEM IMPORTANT QUESTIONS

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UNIT – I

10 Hours

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP

Total Quality Management (TQM): Definition, elements, philosophies

ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines

Quality by design (QbD): Definition, overview, elements of QbD program, tools

ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration

NABL accreditation : Principles and procedures

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DEPTH OF BIOLOGY 10 MARKS QUESTION

1. Define TQM and discuss its elements philosophies
2. Give a detailed note on ICH guidelines and define its purpose, participants and process of harmonization
3. Give a brief overview of QSEM

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05 MARKS QUESTION

1. Discuss the benefits , elements and steps for registration of ISO 9000 and ISO 14000

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DEPTH OF BIOLOGY 02 MARKS QUESTION

1. Define quality assurance
2. Explain QbD [quality by design]
3. Define NABL accreditation [also in 5 marks]
4. Define GMP **DEPTH OF BIOLOGY**
5. What is the purpose of ICH guidelines
6. Define quality control
7. Define TQM and its elements
8. Benefits of ISO 9000 / ISO 14000
9. What is QSEM?

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UNIT - II

10 Hours

Organization and personnel: Personnel responsibilities, training, hygiene and personal records.

Premises: Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

Equipments and raw materials: Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

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10 MARKS QUESTION

1. Discuss the equipment selection, purchase, specification and also its maintenance [also in 5 marks] DEPTH OF BIOLOGY

DEPTH OF BIOLOGY 05 MARKS QUESTION

1. Discuss the design, construction, maintenance and control of contamination of the premises

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DEPTH OF BIOLOGY 02 MARKS QUESTION

1. Explain contamination and its control
2. Different source of contamination

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UNIT – III

10 Hours

Quality Control: Quality control test for containers, rubber closures and secondary packing materials.

Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities

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DEPTH OF BIOLOGY 10 MARKS QUESTION

1. Discuss the quality control test for containers and rubber closure – [also in 5 marks]
2. Explain general provisions, organization and personnel for GLP [good laboratory practices]
3. Discuss the protocol of conduct of a non-clinical laboratory study

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DEPTH OF BIOLOGY 05 MARKS QUESTION

1. Discuss the general provision of GLP

DEPTH OF BIOLOGY 02 MARKS QUESTION

1. Define GLP
2. Explain test & control article
3. What are the different quality control test for container . Give example

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UNIT – IV

08 Hours

Complaints: Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.

Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

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DEPTH OF BIOLOGY 10 MARKS QUESTION

1. Explain the document maintenance in pharmaceutical industry

05 MARKS QUESTION

1. Explain recalling and waste disposal
2. Define complaints
3. Handling of return good
4. Give a short note on SOP
5. Batch formula record
6. Quality audit
7. Distribution records
8. Quality documentation and quality review

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DEPTH OF BIOLOGY 02 MARKS QUESTION

1. Define SOP
2. Batch formula record
3. Define quality review
4. Recalling and waste disposal

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UNIT – V

07 Hours

Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.

Warehousing: Good warehousing practice, materials management

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DEPTH OF BIOLOGY 10 MARKS QUESTION

1. Discuss the general principle of analytical method validation
2. Discuss introduction, definition and general principle of calibration and validation [also in 5 marks]

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05 MARKS QUESTION

1. Good warehousing practice
2. Types of validation
3. Discuss importance, types and scope of validation
4. Discuss qualification of UV- visible spectrophotometer
5. Explain calibration of pH meter

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1. Define calibration and validation
2. Explain good ware housing practice
3. Write the types of validation
4. Give scope and importance of validation

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