

[This question paper contains 2 printed pages.]

Your Roll No.....

Sr. No. of Question Paper : 4652

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Unique Paper Code : 2176000003

Name of the Paper : SEC : Lab Testing and Quality Assurance

Name of the Course : All courses

Semester : II/IV/VI

Duration : 1 Hour

Maximum Marks : 30

Instructions for Candidates

1. Write your Roll No. on the top immediately on receipt of this question paper.
2. Attempt **two** questions in all.

1. a) Choose the correct statement:

- Regulatory authority which controls the regulation of Drugs and cosmetics in India is
 - i) FSSAI
 - ii) CDSCO
 - iii) RBI
 - iv) SEBI
- GMP guidelines are mandatory for
 - i) Toy manufacturing
 - ii) Textile production
 - iii) Pharmaceutical manufacturing
 - iv) Furniture making
- The concept of quality is based on
 - i) Meeting luxury goods standards
 - ii) Productivity excellent products
 - iii) Confirming to the requirement & specifications
 - iv) Maintaining uniformity of design
- Poor quality in a design project is likely to directly effect the
 - i) Manufacturing
 - ii) Advertising
 - iii) Overhead
 - iv) Cost and schedule

P.T.O.

- The primary component of quality management are quality
 - i) inspection, certification and validation
 - ii) planning, assurance and control
 - iii) reliability, maintainability and availability
 - iv) insurance, assurance and warranty industry.
- b) Discuss about the major subsectors in Life Sciences industry.
- c) Explain the role of Pharmaceutical industry in drug development. 5,5,5
- 2. a) How do you handle and dispose off hazardous chemical in the laboratory? Explain it with example.
- b) What is the difference between accuracy and precision.
- c) How is spectroscopy useful in quality control of drugs molecules. 5,5,5
- 3) a) What should be the appropriate conditions for a good sample preparation?
- b) Give a brief account about key guidelines in sample handling.
- c) What is productivity concept? and its importance. 5,5,5
- 4) Write short notes on (any three)
 - i) Statistical analysis of laboratory data
 - ii) Calibration
 - iii) Measurements
 - iv) Quality Certification 5,5,5