



RAN - 2203000205030075

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**B. Sc. (Microbiology) (Sem. - V) Examination March - 2023**

**Microbiology**

**GE1 : Quality Control and Quality Assurance (IDS) (NEW)**

**Time: 2 Hours ]**

**[ Total Marks: 50**

**सूचना : / Instructions**

(1)

नीचे दृश्यावलोकन निशानीवाणी विगतो उत्तरवही पर अवश्य लभवी.  
**Fill up strictly the details of signs on your answer book**

Name of the Examination:  
☛ **B. Sc. (Microbiology) (Sem. - V)**

Name of the Subject :  
☛ **Microbiology GE1 : Quality Control and Quality Assurance (IDS) (NEW)**

Subject Code No.: **2203000205030075**

Seat No.:

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Student's Signature
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- (2) Figures to the right indicate full marks of the question.  
(3) Draw neat and labeled diagrams whenever necessary.

**Q. 1 Give specific answers.**

**(12)**

- a. Define:
  - i) Drug interference
  - ii) Post analytical errors
- b. Differentiate between Accreditation and Certification.
- c. What do you mean by NABL? State its two objectives.
- d. State any two reasons that justify the auditing in pharmaceutical / microbiology industries.
- e. What is the full form of HACCP? State its one significance.
- f. State any two reasons that justify the need for microbiological risk assessments in laboratory.

**Q. 2 Explain/Comment on any two of the following. (12)**

- a. Comment on: QLPS define quality of all aspects of the work performed by the laboratory.
- b. Explain: Good auditors share essential attributes.
- c. Discuss: Biological safety cabinet as important equipment in laboratory.

**Q. 3 Attempt in detail any two of the following. (16)**

- a. Elaborate CLSI as global, standards developing organization.
- b. What are the purposes of auditing the manufacturing process? Discuss how raw materials and packaging materials are important part of product-based audit?
- c. Justify: Biosafety level 1 and 2 different codes of practice.

**Q. 4 Write short note on any two of the following. (10)**

- a. Internal Quality Control.
  - b. Quality Assurance (QAS).
  - c. Importance of FMEA and FRACAS.
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