

Maharshi Karve Stree Shikshan Samstha's

Smt. Hiraben Nanavati Institute of Management & Research for Women

INTERNAL EXAMINATION – Sem II – (Jan- July 2026)

SUBJECT : Quality Assurance and Control Management in Pharma

SUBJECT CODE: PHM 14

Date: 13-05-2026

Pattern : 2024

Duration : 150 min

Max Marks : 50

Instructions for students :

- Marks are indicated for each question.
 - Handwriting should be eligible for evaluation.
 - Marks will be given for quality, not quantity.
-

Q.1] Answer the following questions

(2 Marks Each)

(10 Marks)

- Define Quality Assurance (QA) and Quality Control (QC).
- List any four principles of Quality Management Systems in pharmaceuticals.
- What is Good Manufacturing Practice (cGMP)?
- Name any two analytical techniques used in quality control.
- Match the following:

Column A

Column B

- | | |
|------------------|------------------------------------|
| 1. Six Sigma | a. Continuous improvement |
| 2. Kaizen | b. Defect reduction |
| 3. cGMP | c. Manufacturing quality standards |
| 4. Quality Audit | d. Evaluation of processes |

Q.2] Attempt any Two (5 Marks Each)

(10 Marks)

- Compare Quality Assurance (QA) and Quality Control (QC).
- Summarize the importance of quality audits in pharmaceutical manufacturing.
- Contrast Good Laboratory Practices (GLP) and Good Clinical Practices

Q.3] Attempt any One (10 Marks)

(10 Marks)

- Explain the quality management systems in pharmaceuticals, including regulatory guidelines (FDA, EMA) and responsibilities of QA and QC departments.
- Demonstrate the role of cGMP, SOPs, and quality documentation in ensuring product quality in pharmaceutical manufacturing.

Q.4] Attempt any One

(10 Marks)

a) A pharmaceutical company is facing frequent product quality failures. Analyse the situation using quality risk management and quality control techniques, and suggest corrective actions.

OR

b) Analyse the strategic issues in quality management, including data integrity, compliance challenges, and the impact of regulatory requirements on pharmaceutical companies.

Q.5] Answer the following (any one)

(10 Marks)

a) Devise a quality implementation plan for a pharmaceutical manufacturing unit using tools like Six Sigma, Lean Six Sigma, and 5S, ensuring process optimization and compliance.

OR

b) Create a plan to integrate digital technologies (AI, IoT, data analytics) into pharmaceutical quality assurance systems to improve efficiency and reliability.