

QP Code: 626006

Reg. No.....

**Sixth Semester B. Pharm Degree Supplementary Examinations
March 2026**

Pharmaceutical Quality Assurance

(2017 Scheme)

Time: 3 Hours

Max. Marks: 75

- *Answer all questions to the point neatly and legibly • Do not leave any blank pages between answers • Indicate the question number correctly for the answer in the margin space*
- *Answer all parts of a single question together • Leave sufficient space between answers*
- *Draw diagrams wherever necessary*

Essays

(2x10=20)

1. Discuss in detail, the concept of Quality by Design (QbD) and its importance.
2. Explain purchase specifications and maintenance of stores for raw material.

Short Notes

(7x5=35)

3. Mention the steps for registration under ISO 14000.
4. Write a note on personnel responsibilities.
5. Describe the quality control tests for rubber closures.
6. Explain the concept and process of quality audit.
7. Materials management in warehouse
8. How sterile area is maintained in pharmaceutical industries.
9. Describe the concept of quality management, in general.

Answer Briefly

(10x2=20)

10. Write any two philosophies of TQM.
11. Compare Quality Assurance (QA) versus Quality Control (QC).
12. Explain calibration of pH meter.
13. SOP on complaint handling.
14. Compare GMP versus GLP.
15. What QC tests for secondary packing materials.
16. Enlist the documents maintained in the pharmaceutical industry.
17. What do you mean by quality review.
18. Write a note on QSEM.
19. Differentiate between calibration and validation.
