

QP Code: 626006

Reg. No.....

**Sixth Semester B. Pharm Degree Regular/Supplementary
Examinations November 2025
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. Define ICH Guidelines, explain the purpose, and a brief overview of QSEM with special emphasis on Q-series.
2. Explain the design, construction, and layout of a pharmaceutical industry.

Short Notes

(7x5=35)

3. Enumerate and describe the steps for registration under ISO 9000.
4. Discuss sanitation and control of contamination.
5. Describe disqualification of testing facilities.
6. Explain the handling of returned goods.
7. Elaborate on the maintenance of stores for raw materials.
8. Explain calibration of pH meter.
9. Discuss the process of analytical method validation.

Answer Briefly

(10x2=20)

10. Define SOP and its importance.
11. What is NABL accreditation.
12. Describe batch formula record.
13. Explain elements of total quality management.
14. Mention the advantages of GLP.
15. Quality control test for rubber closures.
16. What is quality audit.
17. What are the contents of distribution records.
18. Mention the tools for implementing QbD.
19. Write a note on the principles of qualification.
