

QP Code: 626006

Reg. No.....

**Sixth Semester B. Pharm Degree Regular/Supplementary
Examinations February 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. Discuss various types of validation
2. Explain the principles of total quality management

Short Notes

(7x5=35)

3. Describe the organization and functioning of GLP facility
4. Write a note on ISO 9000
5. Write procedure for NABL accreditation
6. Write protocol for conduct of a nonclinical laboratory study
7. Write a note on material management
8. How a pH meter will be calibrated
9. Discuss the process of equipment selection and purchase

Answer Briefly

(10x2=20)

10. State the purpose of ICH guidelines
11. Batch formula record
12. Define quality assurance
13. Enlist the scope for validation
14. Distribution records
15. List the parameters in analytical method validation
16. Define quality by design
17. List the responsibilities of QC personnel
18. What is QSEM
19. Write a note on SOP
