

QP Code: 626006

Reg. No.....

**Sixth Semester B. Pharm Degree Regular/Supplementary  
Examinations February 2024  
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. Explain the quality control tests for secondary packaging materials
2. Discuss the tools and elements of QbD program

**Short Notes**

**(7x5=35)**

3. Explain the handling of return goods and waste disposal
4. Discuss the steps involved in validation master plan
5. Write a note on ICH stability testing guidelines
6. Explain calibration of pH meter
7. Explain types of quality audit
8. Explain disqualification of testing facilities
9. How a plant layout will be designed

**Answer Briefly**

**(10x2=20)**

10. List the parameters in analytical method validation
11. What is GMP
12. Elements of TQM
13. Write a note on the principles of qualification
14. What is photo stability testing
15. Role of documentation in quality control
16. Define warehouse
17. What is a non-clinical laboratory
18. What is confirmed complaints
19. Define quality review

\*\*\*\*\*