

QP Code: 626006

Reg. No.....

**Sixth Semester B. Pharm Degree Supplementary Examinations
May 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. Describe the principles and procedure for NABL accreditation
2. Explain the procedure for handling complaints and recall in a pharmaceutical industry

Short Notes

(7x5=35)

3. Write a note on ISO 14000
4. How sterile area is maintained in manufacturing unit
5. Explain qualification of UV – Visible spectrophotometer
6. Write a note on rubber closures
7. Explain standard operating procedure
8. Differentiate batch and master formula record
9. Explain personnel responsibilities and hygiene

Answer Briefly

(10x2=20)

10. Explain elements of QbD program
11. Define retrospective validation
12. Define quality control
13. Name the evaluation tests for plastic containers
14. Define calibration
15. List the parameters in analytical method validation
16. What is GLP
17. Explain material management in warehouse
18. Explain disqualification of testing facilities
19. Discuss control of contamination in sterile areas
