

QP Code: 626006

Reg. No.....

**Sixth Semester B. Pharm Degree Supplementary Examinations
January 2022**

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 on standard operating procedure and write its significance for manufacturing process.
2. Give an account of QSEM with special emphasis on Q-series guidelines.

Short Notes

(7x5=35)

3. Explain functions of good warehousing practice.
4. Design the sterile area for pharmaceutical industry.
5. Briefly note the elements and philosophy of total quality management
6. Quality documentation and how records are distributed.
7. Explain the quality control test for secondary packing materials.
8. Explain validation master plan
9. Define the term ISO 9000 and give its element and benefits

Answer Briefly

(10x2=20)

10. Define quality assurance.
11. Explain the term quality review.
12. Explain the general principles of good laboratory practice.
13. Good manufacturing practice.
14. Name the different types of validation.
15. Explain reports and documents.
16. What are the different contamination source in pharma industry.
17. Give the importance of validation.
18. What are the different types of pharmaceutical waste.
19. Explain the types of equipment maintenance.
