QP Code: 626006 **Reg. No……**

Sixth Semester B. Pharm Degree Supplementary Examinations
October 2023
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 the concept of Material management and good warehousing practice in detail.
2. Describe the terminology of GLP and its emphasis on the provisions, organization, personnel, equipment and facility procedures followed in pharmaceutical industries.

Short Notes **(7x5=35)**

3. State the procedure to follow to obtain ISO 9000 certification.
4. Explain the evaluation of complaints and waste disposal.
5. Give the quality control test for containers and rubber closures.
6. Explain general principles of Analytical method Validation.
7. What are the elements and tools of QbD Program.
8. Explain in detail about the document maintenance in pharmaceutical industry.
9. Explain the importance and scope of validation.

Answer Briefly **(10x2=20)**

10. Classify the different types of audit.
11. At which condition revalidation is required.
12. How to Control the contamination in sterile area.
13. Explain the types of records.
14. List out the benefits of ISO 14000.
15. Define installation qualification and operational qualification.
16. Explain the quality control parameters for rubber and closures.
17. Explain purchase specification.
18. Define quality review.
19. Describe briefly about the plant layout.

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