QP Code: 626006 **Reg. No……**

Sixth Semester B. Pharm Degree Supplementary Examinations
June 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. Write the principles and procedure of NABL accreditation
2. Explain the importance of personnel responsibilities, training, hygiene and personal records in relation to quality assurance.

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

3. Describe the purpose of ICH guidelines and the process of harmonization.
4. Express your opinion on good warehousing practice.
5. Discuss the protocol for conduct of a non-clinical laboratory study.
6. Describe the master formula record.
7. Explain quality review and quality documents.
8. Define validation and explain its types.
9. Define calibration and explain the calibration of the pH meter.

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

10. Compare ISO 9000 versus ISO 14000.
11. Briefly describe any two elements of TQM.
12. Discuss control of contamination in sterile areas.
13. Classification of sterile area.
14. Describe any one quality control test for glass containers.
15. Enlist the principles of GLP.
16. Define complaints and mention their types.
17. How waste disposal in pharmaceutical industries take place.
18. What is validation master plan.
19. What is the procedure to recall the products from market.

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