

QP Code: 626006

Reg. No.....

**Sixth Semester B. Pharm Degree Regular/Supplementary  
Examinations July 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. Define quality control and write the detailed procedure for NABL accreditation.
2. Explain the construction, sanitation, environmental control of premises.

**Short Notes**

**(7x5=35)**

3. Define calibration and how will you calibrate the pH meter.
4. Explain batch formula record.
5. Discuss the steps involved in the registration of ISO 14000.
6. Explain the utilities and maintenance of sterile area.
7. Give in detail about benefits of standard operating procedure.
8. How will you maintain stores for raw materials.
9. Types of recalls.

**Answer Briefly**

**(10x2=20)**

10. Explain any two important tools of quality by design.
11. Explain photo stability testing guideline.
12. Explain the training given to personnel in an organization.
13. Give the general principle of qualification.
14. Brief any two-objectives of documents.
15. Explain the different types of validation.
16. Define operational qualification.
17. Explain the different type of secondary packaging materials.
18. Explain the difference between confirmed and non-confirmed complaints.
19. How to prevent contamination and deterioration in warehouse.

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