**QP Code: 626006** **Reg. No……**

# Sixth Semester B. Pharm Degree Regular/Supplementary Examinations May 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. How to write an effective validation master plan.
2. ISO 9000 and ISO 14000 certification: how to get it and why.

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

3. Just how to implement the good laboratory practice in new pharma industry.
4. How to design the plant layout for sterile area.
5. Explain the personnel responsibilities in the organization.
6. Discuss the general principles of calibration qualification and validation.
7. Explain the protocol for conduct of a non-clinical laboratory study.
8. Discuss about the principles and procedures of NABL accreditation.
9. Explain the elements and philosophies of total quality management.

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

10. Quality control test for containers
11. Define validation as per USFDA.
12. Write about the purchase specification
13. list out the types of equipment qualification
14. In grade A sterile area how many 0.5-to-5-micron number of particles permitted per cubic meter equal to or above
15. Expand HEPA and LAF.
16. Explain photo stability testing guideline.
17. List out the benefits NABL accreditation.
18. Classify the types of quality audit.
19. Elements of QbD

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