QP Code: 626006 **Reg. No…….**

Sixth Semester B. Pharm Degree Regular Examinations May 2021
Pharmaceutical Quality Assurance

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 in detail about principle and procedures of NABL accreditation
2. Summarize how to handle the complaints and recall in pharma industry as per WHO guidelines

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

3. Discuss the infrastructural facilities and equipment's required for establishment of non- clinical testing laboratory.
4. Explain the handling of return goods and waste disposal.
5. Transcribe the general principles of calibration and qualification.
6. How to maintain the raw material purchase specification and store.
7. Discuss the steps involved in validation master plan.
8. Explain the elements and philosophies of total quality management.
9. In what way to perform stability testing as per ICH guidelines.

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

10. Define quality assurance.
11. List out the parameters involved in the analytical method validation.
12. Explain quality management concept.
13. Classify the types of quality audit.
14. List out the benefits of ISO 14000
15. Explain purchase specification.
16. What are the steps required for the maintenance of sterile area.
17. Describe briefly about the master formula record.
18. Define quality review.
19. Describe briefly about distribution of records.

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