**DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE**
**End Semester Examination – Winter 2022**

**Date: 20/02/2023**

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| **Course :** | **B. Pharmacy** | **Sem :** | **VI** |
| **Subject Name :** | **Quality Assurance** | **Subject Code :** | **BP 606 T** |
| **Max Marks :** | **75** | **Duration :** | **3 Hr.** |

**Instructions:**

1. **All questions are compulsory**
2. **Draw diagrams / figures wherever necessary**
3. **Figures to right indicate full marks**

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**Q. 1. Objective Type Questions (Answer all the questions)** **(10 x 2) = 20**

**i)** Enlist benefits of ISO14000.

**ii)** Define NABL accreditation.

**iii)** Give the difference between QA and QC.

**iv)** Enlist Q series of ICH Guidelines.

**v)** What is contamination and cross contamination?

**vi)** Define TQM. Discuss its advantages.

**vii)** What is Batch Formula Record?

**viii)** Classify packaging material used in the pharmaceutical industry with example.

**ix)** Define Qualification and Calibration.

**x)** What is warehousing and material management?

**Q. 2. Long Answers (Answer 2 out of 3)** **(2 x 10) = 20**

**i)** Discuss the importance of Good Laboratory Practices. Explain protocol content of Non-clinical laboratory study.

**ii)** What is Validation? Explain types of validation and discuss validation master plan.

**iii)** Define Quality control. Explain quality control test for containers.

**Q. 3. Short Answers (Answer 7 out of 9)** **(7 x 5) = 35**

**i)** Define airlock. Enlist different types of airlock and explain their working.

**ii)** Discuss in brief different elements of GLP.

**iii)** Discuss the QSEM guidelines as per ICH.

**iv)** Write about the concept of quality by design (QbD) in pharma industry.

**v)** Write a note on Master Formula Record.

**vi)** Discuss qualification of UV-Visible Spectrophotometer.

**vii)** Explain steps involved in complaint handling.

**viii)** Explain various documents maintained by quality control department.

**ix)** Explain about personnel responsibilities, training and hygiene.

**------END OF THE PAPER------**