DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE

End Semester Supplementary Examination - Winter 2023

Date: 10/01/2024

Course:	**B. Pharmacy**	**Sem** :	**VI**
Subject Name:	**Quality Assurance**	**Subject Code** :	**BP606T**
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**

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

i) Give difference between QA and QC.

ii) Enlist Q series of ICH guidelines.

iii) Write down the importance of documentation in pharma industry.

iv) Define NABL acceleration.

v) What is mean by warehousing

vi) What is SOP?

vii) Enlist benefits of ISO 9000.

viii) What is mean by complaints and recalling?

ix) Classify packing material with examples.

x) Define GMP and give its importance.

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

i) What is mean by BFR and MFR? Explain them in detail.

ii) Write the principles of Calibration, Validation and Qualification.

iii) How to maintain organization and personal in pharmaceutical industry.

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

i) Explain in detail Quality control test for containers.

ii) Which are the various elements of TQM?

iii) Explain QSEM guidelines as per ICH.

iv) Explain steps involved in complaint handling.

v) What is mean by premises in the consideration of control of contamination in pharmaceutical industry?

vi) Discuss in brief different elements of GLP.

vii) Write a note on QbD.

viii) Mention the various steps for registration of ISO 9000 and 14000.

ix) Give the general principles of Analytical Method Validation.

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