

DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE
End Semester Supplementary Examination - Winter 2023

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Date: 10/01/2024

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Course: **B. Pharmacy**
Subject Name: **Quality Assurance**
Max Marks : **75**

Sem : **VI**
Subject Code : **BP606T**
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) 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? <https://pharmacyindia.co.in/>
- 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.

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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.

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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.

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- 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.

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

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