

School of Medical and Allied Sciences

Pharmacy
ETE - Jun 2023

Time : 3 Hours

Marks : 75

Sem VI - BP606T/BPHT6006

Quality Assurance Theory

Your answer should be specific to the question asked

Draw neat labeled diagrams wherever necessary

1. What is a quality assurance and concept of quality assurance. K1 CO1 (2)
2. Illustrate Master Formula Record? K2 CO4 (2)
3. Define complaints in pharmaceutical industry? K1 CO4 (2)
4. Illustrate the importance of records and reports in GLP? K2 CO3 (2)
5. What should be the purchase specification of Equipments? K1 CO2 (2)
6. Explain Good Warehousing Practice? K2 CO5 (2)
7. Explain the purpose of Harmonization? K2 CO1 (2)
8. List the Quality control test of secondary packaging material? K1 CO3 (2)
9. Define Calibration? K1 CO5 (2)
10. Explain the importance of personnel training? K2 CO2 (2)
- 11) Construct the principle and procedure of NABL accreditation? K3 CO1 (5)

OR

- Develop the brief about elements of QbD program? K3 CO1 (5)
12. Plan the responsibilities of personnels in GMP? K3 CO2 (5)
 13. Develop the Quality Control test for glass containers? K3 CO3 (5)
 14. Classify the Key personnel of organization. K4 CO2 (5)

OR

- Categorize the importance of personnel training and personal records.
15. List the Q-series guidelines of QSEM? K4 CO1 (5)
 - 16) List the levels of Organisation of GLP? K4 CO3 (5)

OR

- Describe the protocol for conduct of a non clinical laboratory study? K4 CO3 (5)
17. Discuss the different models for experimental design. K6 CO6 (5)
 18. Explain the procedure for handling and evaluation of complaints? K5 CO4 (10)
 - 19) Elaborate the general principles of Calibration, Validation and Qualification? K6 CO5 (10)

OR

- Elaborate the general principles of analytical method of validation? K6 CO5 (10)