

School of Medical and Allied Sciences

Bachelor of Pharmacy
Semester End Examination - Aug 2024

Duration : 180 Minutes
Max Marks : 75

Sem VI - BPHT6006 - Quality AssuranceGeneral Instructions

Answer to the specific question asked

Draw neat, labelled diagrams wherever necessary

Approved data hand books are allowed subject to verification by the Invigilator

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|-----------|--|--------|
| 1) | Relate the term cartons are tested for quality control. | K2(2) |
| 2) | Illustrate about the crushed glass test. | K2(2) |
| 3) | What are distribution records? | K1(2) |
| 4) | Illustrate about the validation of disinfection of premises. | K2(2) |
| 5) | Define prospective validation. | K1(2) |
| 6) | Illustrate the note on positive and negative pressure rooms. | K2(2) |
| 7) | What do you mean by product recall ? | K1(2) |
| 8) | Illustrate the aspects should be considered while equipment selection. | K2(2) |
| 9) | Define auditing. | K1(2) |
| 10) | Define conformance quality. | K1(2) |
| 11) | Organize the critical elements of buildings and infrastructure required for GMP compliance | K3(5) |
| OR | | |
| | Compare the steps involved in obtaining ISO 9000 certification with those required for another ISO standard, such as ISO 14001 | K3(5) |
| 12) | Identify the protocol for ICH stability testing. | K3(5) |
| 13) | Anlyze about the premises requirements in a warehouse. | K4(5) |
| 14) | Develop a note on master formula record. | K3(5) |
| 15) | Organize the key benefits and scope of NABL accreditation | K4(5) |
| 16) | Examine the quality control tests for paper and board. | K4(5) |
| OR | | |
| | Anlyze about the premises requirements in a warehouse. | K4(5) |
| 17) | Simplify about the procedure of NABL accreditation. | K4(5) |
| 18) | Build a brief review on records and reports maintenance as per GLP regulations. | K6(10) |

19) Importance of quality audit.

K5(10)

OR

Write about the evaluation of complaints.

K5(10)