

School of Medical and Allied Sciences

Bachelor of Pharmacy

Semester End Examination - Nov 2023

Duration : 180 Minutes

Max Marks : 75

Sem VII- BPHT7002- Industrial Pharmacy II

General 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) | Explain about certificate of Pharmaceutical product. | K2 (2) |
| 2) | Demonstrate about the significance of Quality by design. | K2 (2) |
| 3) | What do you understand by TGA? | K1 (2) |
| 4) | Explain the difference between Receiving Unit and Sending Unit in Technology Transfer. | K2 (2) |
| 5) | What do you understand by Electronic documents and signatures? | K1 (2) |
| 6) | Demonstrate the need of technology transfer. | K2 (2) |
| 7) | What is the main role of a Regulatory body? | K1 (2) |
| 8) | Demonstrate the term API with some examples. | K2 (2) |
| 9) | Recall the term IND. | K1 (2) |
| 10) | What is the significance of pilot plant scale up? | K1 (2) |
| 11) | Build a note on the process of evaluation of tablets as per Quality by design. | K3 (5) |
| OR | | |
| | Organize a note on Kaizen cycle for continuous improvement. | K3 (5) |
| 12) | Organize a note on Level 1 change in component and composition as per SUPAC guidelines. | K3 (5) |
| 13) | Analyze about IND filing process for drug approval. | K4 (5) |
| 14) | Organize a note on the role of Platform technology in Pharmaceutical product development. | K3 (5) |
| 15) | Assume a note on commercialization of technology. | K4 (5) |
| 16) | Simplify the organogram of CDSCO. | K4 (5) |
| OR | | |
| | Analyze about the process of Drug Regulation. | K4 (5) |
| 17) | Assume the basic principles of ISO 9001:2008. | K4 (5) |
| 18) | Develop a note on Common Technical Document. | K6 (10) |
| 19) | Conclude a note on the four pillars of GLP in Pharmaceutical Industry. | K5 (10) |

OR

Conclude a note on the process of getting the COPP.	K5 (10)
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