

School of Medical and Allied Sciences

Department of Pharmacy

Sessional I

Exam Date: 27 Sep 2023

Time : 90 Minutes

Marks : 30

Sem VII- BPHT7002- Industrial Pharmacy II

Your answer should be specific to the question asked

Draw neat labeled diagrams wherever necessary

- 1) What do you understand by pre-exhibit batch? K1 (2)
 - 2) Interpret the three levels of changes as per SUPAC guidelines. K2 (2)
 - 3) Demonstrate the process of technology transfer from R & D to production. K2 (2)
 - 4) What do you understand by Pilot batch? K1 (2)
 - 5) Illustrate about parameters of qualification of equipments. K2 (2)
 - 6) Organize a note on three levels of changes as per SUPAC guidelines. K3 (5)
 - 7) Analyze about technology transfer of starting materials. K4 (5)
- OR**
- Simplify about WHO guidelines for technology transfer. K4 (5)
 - 8) Explain the general considerations for Pilot plant scale up. K5 (10)
- OR**
- Appraise a note on the bioequivalence study as per SUPAC guidelines. K5 (10)