



DBX-MQA-202-T Seat No. _____

Master of Pharmacy (Sem. II) Examination

July - 2022

MQA-202T : Pharmaceutical Validation

Time : 3 Hours]

[Total Marks : 75]

1 Answer the following questions. 20

- (1) What is the Difference between calibration and validation?
- (2) What is the objective and principle of cleaning validation?
- (3) Define different types of qualifications.
- (4) How can we Check the performance of HPTLC?
- (5) What is 21CFR part 11 ?
- (6) What is the duration of copyright and Patent protection in India?
- (7) What is WIPO? Write its purpose.
- (8) What is Direct and Indirect Patent Infringement?
- (9) What is HVAC system in Validation of Utility systems?
- (10) What is Significance of transfer technology?

2 Answer the following questions : (ANY TWO) **20**

- (1) What is IPR? Explain Procedure for Grant of Patent and PCT application.
- (2) Explain qualification of HPLC and DSC.
- (3) What you understood by Concurrent & Retrospective Validation? Explain USFDA guidelines on Process Validation.

3 Answer the following questions : (ANY SEVEN) 35

- (1) What is cleaning validation? Describe cleaning procedure.
- (2) Explain role of IP in Pharmaceutical Industry.
- (3) Describe Validation of facilities in sterile plant.
- (4) Describe sampling technique in cleaning validation.
- (5) Explain in brief Validation Master Plan.
- (6) Explain Qualification of UV-Visible spectrophotometer.
- (7) Explain analytical method validation parameters as per ICH.
- (8) Explain equipment qualification of Fluid Bed and Tray dryers.
- (9) Explain performance Qualification of tap density tester, Disintegration tester, Dissolution test apparatus.
