



DAQ-BP-606T-A

Seat No. _____

M. P. M. (Sem. VI) Examination

April / May - 2022

Quality Assurance

Time : 3 Hours]

[Total Marks : 75

- Instructions:** (1) Figures to the right indicate marks.
(2) Draw neat and clean diagram when required.

1 Answer the following questions. **10×2=20**

- (1) Write any four elements of TQM.
- (2) Define Quality Assurance and Quality Control
- (3) Write importance of SOP.
- (4) Differentiate calibration and qualification.
- (5) Define Quality by Design.
- (6) Enlist Q series of ICH guideline.
- (7) Name different types of validation.
- (8) Enlist quality documents.
- (9) Define and classify containers.
- (10) What is the importance of Distribution record ?

2 Answer any two out of the following questions : **2×10=20**

- (1) Explain objective and scope of GLP.
- (2) Write a detailed note on Quality Audit.
- (3) Write a detailed note on BMR and MFR.

3 Answer any two out of the following questions : **7×5=35**

- (1) Write a detailed note on ISO 9000 and ISO 14000.
- (2) Define calibration. Explain the procedure for calibration of PH meter.
- (3) Give a detailed note on NABL.
- (4) Explain QC test for secondary packaging material.
- (5) Define complaints. Write types of complaints and how to handle it.
- (6) Explain good warehousing practice.
- (7) What are the requirements for environment control and lay out of sterile manufacturing area.
- (8) Explain various method validation parameters.
- (9) Write in brief about equipment and raw materials as per GMP guideline.
