



MA-M.Q.A.-102T Seat No. _____

**M. Pharm. (Sem. I) (CBCS)
(Quality Assur. External) Examination
December – 2017**

MQA-102T : Quality Management System (Theory)

Time : 3 Hours]

[Total Marks : 75

- Instructions :** (1) Figure to the right indicates marks.
(2) Draw neat and clean diagrams as required.

1 Answer the following questions : (ten) **10×2=20**

- (a) Define Quality.
- (b) Define Benchmarking.
- (c) State the importance of IPQC
- (d) What are objectives of Change Management?
- (e) What is NABL certification and accreditation?
- (f) What is Statistical Process control?
- (g) What are the Dimensions of Quality?
- (h) Define Total Quality Management.
- (i) Define customer and customer focus.
- (j) What do you mean by Quality by Design?
- (k) Define Knowledge management.

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

- (a) Discuss stability testing of drug substances according to ICH guideline.
- (b) Explain quality policy and objectives, strategic planning and implementation.
- (c) Briefly explain risk assessment, risk control, risk review, risk management tools, risk ranking and filtering according to ICH Q9 guidelines.

3 Answer any **seven** out of following :

7×5=35

- (a) Write a note on Classification of customers, and Factors affecting customer perception.
- (b) Write at length on Total Quality Management (TQM).
- (c) Explain Pharmaceutical Quality Management - ICH Q10.
- (d) Write a short note on Quality by Design according to ICH.
- (e) Discuss Deviations, Out of Specifications (OOS) and Out of Trend (OOT).
- (f) Discuss at length Corrective and Preventive Actions (CAPA) in Quality systems.
- (g) Write a short note on Vendor Qualification.
- (h) Explain concepts, Advantages of statistical control and Process capability.
- (i) Briefly explain Reasons, Types, Advantages and Limitations of benchmarking.
