



J-MQA-102-T

Seat No. _____

M. Pharm. (Sem. I) (External) Examination

January - 2020

Quality Assurance : MQA - 102T

(Total Quality Management) (Theory)

Time : 3 Hours]

[Total Marks : 75

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

- (a) What is the composition of ICH Q 10 document?
- (b) Explain PQS according to ICH and ISO.
- (c) What is the importance of IPQC?
- (d) Why is OSHA important to you?
- (e) Define: Customer and Strategy.
- (f) Why need for stability testing?
- (g) Explain the elements of Pharmaceutical development.
- (h) What do you mean by QbD approach?
- (i) What are the dimensions of Quality?
- (j) Enlist factor affecting customer perception.

2 Answer the following question : (any two) **2×10=20**

- (a) Detail note on ICH Q9.
- (b) Write an informative note on CAPA.
- (c) Explain in detail about McKinsey 7s model.

3 Answer the following question : (any seven) **7×5=35**

- (a) Write an informative note on Q 1(B).
- (b) Explain an overview of 21 CFR Part 11.
- (c) Describe Product Recall Chart.
- (d) Explain about the basics of Quality Management according to Total Quality Management (TQM).
- (e) Explain in detail about ICH Q1A.
- (f) Give explanation on Competitive analysis.
- (g) Write a note on Benchmarking and Matrixing.
- (h) Define the term Customer focus. Classify customer. Explain perception of quality and factors affecting customer perception,
- (i) Brief note on SPC.