



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.