

**PARUL UNIVERSITY**  
**FACULTY OF PHARMACY**  
**M.Pharm. Summer 2018 – 19 Examination**

**Semester: 1**  
**Subject Code: MQA102T**  
**Subject Name: Quality Management System**

**Date: 26/04/2019**  
**Time: 10:00am to 1:00 pm**  
**Total Marks: 75**

**Instructions:**

1. Figures to the right indicate maximum marks.
2. Make suitable assumptions wherever necessary.

**Q.1 Essay Type Questions. (any 2 out of 3) (15 Marks Each) (30)**

1. Define Quality; Briefly explain strategy and strategic Quality Management, mission and vision for Quality, Quality police along with objectives.
2. Explain importance of cost of Quality, Briefly explain categories of cost of Quality, models of cost of Quality, optimizing and preventing cost of Quality
3. Explain principle of Six sigma, Briefly explain ISO 9001:2008, ISO 9001:2015, ISO 14001:2004

**Q.2 Short Essay Type Questions. (any 5 out of 6) (5 Marks Each) (25)**

1. Write a note on NABL Certification.
2. Write a short note on TQM.
3. Write a note on McKinsey 7s model in Quality management.
4. Write a note on
  - 1) OSHA guideline
  - 2) 21 CFR part 11
5. Briefly explain CAPA.
6. Write a detail note on ICH guideline for stability testing of drug substance and drug products.

**Q.3 Short Answers. (2 Marks Each) (20)**

1. What is SPC?
2. Write a note on Vendor Qualification.
3. What is self inspection?
4. Write a detail note on HACCP.
5. What is area clearance and Line clearance?
6. Explain types of Benchmarking process.
7. Define terms.
  1. IPQC
  2. Self Inspection
8. Explain Statistical control charts.
9. Differentiate between OOS and OOT.
10. Write a detail note on Batch review and Batch release.