

**PARUL UNIVERSITY**  
**FACULTY OF PHARMACY**  
**M.Pharm. Summer 2018 - 19 Examinations**

**Semester: 1****Subject Code: MQA 103T****Subject Name: Quality Control and Quality Assurance****Date: 27/04/2019****Time: 10.00 am 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. What is GMP, QC and QA. Explain concept and scopes of Quality Control and Quality Assurance. What is the relationship between GMP, QC and QA.
2. Explain finished product and in process quality control tests for capsules.
3. Write a note on Good laboratory Practice.

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

1. What is Good warehousing practices. Describe important requirement of GWP in brief.
2. Describe Organization and personnel according to Schedule M.
3. Describe various analytical test of glass packaging material.
4. What is SOP? Describe its contents.
5. Explain various documents used in Pharmaceutical industry.
6. Explain handling of waste and scrap disposal procedures.

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

1. What is ICH? Classify ICH guidelines.
2. What is patent?
3. Describe change control.
4. What are different categories of complaint?
5. What is recalled product?
6. What is IPQC?
7. What is mix-up?
8. What is CTD?
9. What is the importance of environmental control?
10. What is BMR?