

Roll No.: \_\_\_\_\_

Enrollment No. \_\_\_\_\_

**PARUL UNIVERSITY**

**PARUL INSTITUTE OF PHARMACY**

**M.PHARM FIRST SEMESTER · FIRST INTERNAL EXAMINATION: 2018-19**

**Discipline: Pharmaceutical Quality Assurance**

**Subject Name: Quality Control and Quality Assurance**

**Subject Code: MQA103T**

**Time: 10:00 am to 11:30 am**

**Date: 19/09/18**

**Total Marks: 30**

**Instructions:**

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

Q.1		Long Answers: (Any One)	
	(1)	Describe general requirements according to Schedule M for Warehousing area, Production area and QC area. Describe concept and functions of QA and QC.	10
	(2)	Describe IPQC tests for uncoated tablet.	10
Q.2		Short Answers: (Any Four)	
	(1)	What is ICH? Enlist Q guidelines and explain any one briefly.	05
	(2)	According to Schedule M, what are the requirements for precautions against mix-ups and cross-contamination.	05
	(3)	Describe concept of QA, GMP, GLP and QC.	05
	(4)	Explain guideline for Health, clothing and sanitation of workers in Pharma. Industry.	05
	(5)	Describe IPQC testing for Parenterals.	05

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