

**THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY**

**[M.PHARM 0823]**

**AUGUST 2023  
(APRIL 2023 EXAM SESSION)**

**Sub. Code: 2953**

**M.PHARMACY DEGREE EXAMINATION  
SEMESTER - I (PCI New Regulations 2016)  
PHARMACEUTICAL ANALYSIS - MPA  
PAPER III – PHARMACEUTICAL VALIDATION**

*Q.P. Code: 262953*

**Time : Three hours**

**Answer ALL Questions**

**Maximum : 75 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. Define validation and briefly explain about User requirement specification and change management.
2. Explain the qualification of glassware.

**II. Write notes on:**

**(7 x 5 = 35)**

1. Explain about the calibration preventive maintenance.
2. Describe the cleaning analytical method development.
3. Enumerate the digital significance of 21 CFR part 11.
4. Describe the mechanism for protection of Intellectual property.
5. Illustrate the procedure and cost for international patenting requirement.
6. Explain about Site Acceptance Test.
7. Describe cleaning in place.

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