

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

**[MPHARM 0122]**

**JANUARY 2022  
(APRIL 2021 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 Qualification. Explain about the installation qualification and Operational qualification.
2. a) Write the Calibration procedure for burette and HPLC.  
b) Write in detail about the validation master plan and its importance.

**II. Write notes on:**

**(7 x 5 = 35)**

1. Write a note on Re-qualification.
2. Site acceptance test [SAT].
3. Write an account on streamlining of Qualification.
4. Explain the need of Intellectual property Right and their Economic Importance.
5. Qualification of Electronic balance.
6. Qualification of pH meter.
7. Performance Qualification.

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