

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

[M.PHARM 0524]

**MAY 2024
(APRIL 2024 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. Discuss the validation master plan, advantages of validation and performance qualification.
2. Explain the qualification of UV-Visible Spectrophotometer and HPLC.

II. Write notes on:

(7 x 5 = 35)

1. Validation of HVAC system.
2. Rights and responsibilities of patentee.
3. Site Acceptance Test (SAT).
4. Qualification of Pipette and measuring cylinder.
5. Validation of analytical method used in cleaning.
6. Installation qualification.
7. Write a note on Compressed air and Nitrogen.
