

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

[MPHARM 0921]

**SEPTEMBER 2021
(OCTOBER 2020 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. Give the definition of validation, advantages, streamlining of qualification and validation master plan.
2. Write the qualification of analytical instruments of the following:
 - a) GC.
 - b) UV – Visible spectrophotometer.
 - c) FTIR.

II. Write notes on:

(7 x 5 = 35)

1. Give the advantages of validation.
2. HVAC system.
3. Performance Qualification.
4. Explain the types of patent application.
5. What is the Rights and responsibilities of Patentee.
6. Qualification of Burette and Pipette.
7. Cleaning validation of any one equipment.
