

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

[LQ 0121]

**JANUARY 2021**

**Sub. Code: 2953**

**(APRIL 2020 EXAM SESSION)**

**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 in detail about the Validation of utility system in Pharmaceutical water system & pure steam.
2. Explain in detail about the Qualification of Analytical Instruments (UV-Visible, FTIR, GC and HPLC).

**II. Write notes on:**

**(7 x 5 = 35)**

1. Write a note on Site Acceptance test.
2. Discuss about the Calibration of HPLC.
3. Write a note on Compressed air & nitrogen.
4. Explain about the Qualification of Manufacturing equipment
5. What was the Role of Intellectual property (IP) in Pharmaceutical industry?
6. Briefly explain about Trademark and Copyright.
7. Write the steps to be followed in Cleaning of Equipment.

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