

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

**[LQ 0121]**

**JANUARY 2021**

**Sub. Code: 2957**

**(APRIL 2020 EXAM SESSION)**

**M.PHARMACY DEGREE EXAMINATION**

**SEMESTER-II (PCI New regulations 2016)**

**PHARMACEUTICAL ANALYSIS – MPA**

**PAPER III – QUALITY CONTROL AND QUALITY ASSURANCE**

***Q.P. Code : 262957***

**Time : Three hours**

**Answer ALL Questions**

**Maximum : 75 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. What do you mean by SOP? Write in detail about SOP of different manufacturing process.
2. a) Write note on release of finished product.  
b) Master formula record.

**II. Write notes on:**

**(7 x 5 = 35)**

1. Control on animal house.
2. ICH guidelines.
3. Good Warehousing Practice.
4. Distribution records.
5. Aseptic process control.
6. Quality control test for closures.
7. Environmental control.

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