

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

[LP 957]

NOVEMBER 2019

Sub. Code: 2957

**M.PHARM. DEGREE EXAMINATION**  
**(PCI New regulations 2016)**  
**SEMESTER-II**  
**BRANCH-III – PHARMACEUTICAL ANALYSIS – MPA**  
**PAPER III – QUALITY CONTROL AND QUALITY ASSURANCE**

*Q.P. Code : 262957*

**Time : Three hours**

**Maximum : 75 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. a) Describe in detail about Good Laboratory Practice.  
b) Write note on plant layout and construction of Pharma industry.
2. a) Write note on analysis of raw materials and finished products.  
b) Master formula records.

**II. Write notes on:**

**(7 x 5 = 35)**

1. Write note on Quality Assurance unit.
2. Describe the protocol for conducting non clinical testing.
3. Write note on sanitation in Pharma industry.
4. Write note on in process quality control.
5. Standard operating procedure.
6. Quality audit.
7. Write note on maintenance of sterile area.

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