

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

[M.PHARM 0922]

**SEPTEMBER 2022
(APRIL 2022 EXAM SESSION)**

Sub. Code: 2957

**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. Discuss in detailed on quality, safety, efficacy and multidisciplinary guidelines.
2. Explain the master formula record and batch formula record.

II. Write notes on:

(7 X 5 =35)

1. In-process quality control test for tablets.
2. Sanitation of manufacturing premises.
3. Quality control for secondary packing materials.
4. Premises, location and building requirements for pharma industry.
5. Restrictions on animal house.
6. Need for distribution records in pharma industry.
7. CPCSEA guidelines.
