

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

[MPHARM 0921]

**SEPTEMBER 2021
(OCTOBER 2020 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. a) Write note on GMP.
b) Explain the overview of ICH guidelines with special emphasis on Q-Series.
2. a) Write note on C GMP guidelines for the organisations and personal responsibilities.
b) Good warehousing practices.

II. Write notes on:

(7 x 5 = 35)

1. Quality assurance unit.
2. CPCSEA guidelines.
3. Purchase specifications of raw materials.
4. Batch formula record.
5. Sanitation of manufacturing premises.
6. Release of finished products.
7. Quality control test for containers.
