

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

[LP 355]

OCTOBER 2019

Sub. Code: 2916

**M.PHARM. DEGREE EXAMINATION
FIRST YEAR
BRANCH V – PHARMACEUTICAL ANALYSIS
PAPER IV – QUALITY CONTROL AND QUALITY ASSURANCE**

Q.P. Code : 262916

Time : Three hours

Maximum : 100 Marks

I. Elaborate on:

(2 x 20 = 40)

1. Explain the following term:
 - a) Line clearance.
 - b) Reconciliation of labels.
 - c) Bubble packs.
 - d) Permeation and Leaching.
2. a) Write a detailed note on recent amendments to drugs and cosmetic act and consumer protection.
b) Give a detailed account on plan layout and construction of Pharma industry.

II. Write notes on:

(10 x 6 = 60)

1. What is TQM? Explain in detail.
2. Quality audit.
3. Master formula record.
4. Write note on selection of vendors.
5. Write about the material and management in warehousing.
6. Evaluation of complaints.
7. Disposal of waste procedure and records.
8. Regulatory aspects of drug analysis.
9. Write the process of patent and discuss its significance.
10. SOP of sterilization.
