

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

[LM 355]

MAY 2018

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. a) Write in detail about certification of World Health Organisation.
b) Explain the Import policy and Export of drugs.
2. a) Discuss in detail the term “Good laboratory practices” give stress on the responsibilities of quality control laboratory with regard to protocols and instruments.
b) Write in brief about finished product release.

II. Write notes on:

(10 x 6 = 60)

1. Waste disposal.
2. Batch release document.
3. Methods and equipment involved for Dry Heat Sterilization.
4. SOP for membrane filtration.
5. Explain the concepts of TQM.
6. Quality control for secondary packaging materials.
7. Location and building requirements for Pharma Industry.
8. Training of personnel.
9. Quality control of filling equipment.
10. Write a note on maintenance of stores.
