

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

[LP 953]

NOVEMBER 2019

Sub. Code: 2953

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
BRANCH III – PHARMACEUTICAL ANALYSIS – MPA
PAPER III – PHARMACEUTICAL VALIDATION

Q.P. Code : 262953

Time : Three hours

Maximum : 75 Marks

I. Elaborate on:

(2 x 20 = 40)

1. Define Qualification and briefly explain about Validation process & Master plan.
2. a) Describe in detail about the Global ramification and financial implication.
b) Explain about Intellectual Property Protection (IPP).

II. Write notes on:

(7 x 5 = 35)

1. Write a note on Operational Qualification.
2. Discuss about the Calibration of UV-Visible Spectrophotometer.
3. Describe about the Significance of Transfer Technology.
4. Explain about the Practical aspects regarding maintaining of Patent file.
5. Discuss about Cleaning Validation.
6. Briefly explain about computerized system validation.
7. Give a detail note on Concepts of Intellectual Property
