

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

[LO 953]

MAY 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. Explain the qualification of UV-Visible Spectrophotometer, and HPLC.
2. Write the concepts of Intellectual Property (IP), Intellectual Property Protection (IPP) and Intellectual Property Rights (IPR).

II. Write notes on:

(7 x 5 = 35)

1. Validation Master Plan.
2. Qualification of beaker and burette.
3. Cleaning validation of equipment.
4. 21CFR part II.
5. Significance of transfer Technology (TOT).
6. Installation qualification.
7. Factors affecting choice of IP protection.
