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

[MPHARM 0122] JANUARY 2022 Sub. Code: 2952
(APRIL 2021 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER-I (PCI New regulations 2016)
PHARMACEUTICAL ANALYSIS - MPA
PAPER II – ADVANCED PHARMACEUTICAL ANALYSIS
Q.P. Code : 262952

Time : Three hours Answer ALL Questions Maximum : 75 Marks

I. Elaborate on: (2 x 20 = 40)

1. Elaborate the characterization and Method development for degradation in Pharmaceuticals.

2. Explain the principle, procedure, applications and demerits of the following
   a) Radio immuno assay b) Enzyme immuno assay.

II. Write notes on: (7 x 5 = 35)

1. Classify and write reporting level of residual solvent impurities.
2. Outline PCR studies for gene regulation.
3. Discuss rationale for the reporting and control of degradation products in new drug products.
4. Write the principle and procedure involved in the biological assay of Adsorbed Tetanus Vaccine.
5. Summarize the regulatory requirements for stability testing of Phytopharmaceuticals.
6. Discuss Source and control of elemental impurities.
7. Recall the biological test and assay of Heparin sodium.

****