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

[LQ 0121] JANUARY 2021 Sub. Code: 2952

(APRIL 2020 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. Write the principle and procedures involved in the biological assays of :
   a) Tetanus antitoxin b) Antivenom c) Oxytocin

2. Write the basics of impurity profiling and degradation products including characterization. Explain the methods for the quantification of impurities as per ICH guidelines.

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

1. Write the analytical procedures for H, N and S analysis.
2. Write the basic principles involved in the immunoassays.
3. How do you control Elemental impurities in Pharmaceutical products?
4. Write in detail about the regulatory requirements for Phytopharmaceuticals.
5. Describe the ICH stability guidelines for biological products with suitable example.
6. Explain the finger printing techniques in Phytopharmaceuticals by HPLC/HPTLC.
7. Describe about the principles and applications of Radioimmunoassay.

****