

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

**[M.PHARM 0524]**

**MAY 2024  
(APRIL 2024 EXAM SESSION)**

**Sub. Code: 2952**

**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. Define and classify impurities. Enumerate the degradation products in specifications and qualification. Describe and draw a flow chart showing Schematic representation of quantification Techniques for impurity profiling of drugs.
2. Write the basic principles involved in the immunoassays. Give a flow chart showing production of monoclonal antibodies. Discuss in detail about quantification and applications of immunoassays.

**II. Write notes on:**

**(7 x 5 = 35)**

1. Describe the finger printing techniques in Phytopharmaceuticals by HPLC/HPTLC.
2. Write the general analytical procedures for identification of elemental impurities.
3. Describe about potential sources of elemental impurities.
4. Enlighten the procedure for the biological assay of Tetanus antiserum.
5. Describe in detail about degradant characterization.
6. Explain about the stability testing protocols with important parameters.
7. Give details about the PCR studies for gene regulation.

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