

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

[M.PHARM 0922]

**SEPTEMBER 2022
(APRIL 2022 EXAM SESSION)**

Sub. Code: 2956

**M.PHARMACY DEGREE EXAMINATION
SEMESTER - II (PCI New regulations 2016)
PHARMACEUTICAL ANALYSIS - MPA
PAPER II – MODERN BIO ANALYTICAL TECHNIQUES**

Q.P. Code : 262956

Time : Three hours

Answer ALL Questions

Maximum : 75 Marks

I. Elaborate on:

(2 x 20 = 40)

1. a) Highlight the USFDA guidelines for bioanalytical method validation.
b) Cytochrome P450 based drug interactions.
2. a) Enumerate the sample preparation to study metabolites by Human Liver Microsome.
b) Discuss on Toxicokinetics evaluation in preclinical studies.

II. Write notes on:

(7 x 5 = 35)

1. Write a note on Clinical significance of Bioequivalence studies.
2. Biosimilar products.
3. General principle and procedure involved in Protein Precipitation.
4. What is dissolution and drug release testing?
5. Describe the *in-vivo* assay of drug metabolites.
6. Effect on protein binding interactions.
7. Cell culture media and isolation of cells.
