

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

[MD 0723]

**JULY 2023
(MAY 2023 EXAM SESSION)**

Sub. Code: 2025

M.D. DEGREE EXAMINATION

BRANCH VI – PHARMACOLOGY

**PAPER IV – APPLIED PHARMACOLOGY AND LAWS GOVERNING
DRUG REGULATIONS**

Q.P. Code: 202025

Time: Three Hours

Maximum: 100 Marks

I. Essay:

(2 x 15 = 30)

1. Constitution and Procedure for Registration of Institutional Ethics Committee of your Institution Planning to conduct Clinical Trials. Add a note on roles and responsibilities of Member Secretary and Legal Expert.
2. Discuss in detail about Anti-Obesity Drugs.

II. Short notes:

(10 x 5 = 50)

1. Legislative schedules of Drugs and Cosmetics in India.
2. Phase 0 and Phase I Trials.
3. Drug repositioning and repurposing.
4. Ameliorative therapies toxicity of Anticancer Chemotherapy.
5. Drugs used to treat Mucormycosis.
6. PCSK 9 Inhibitors.
7. Post exposure Prophylaxis of HIV.
8. Mechanism to induce Immune Tolerance.
9. Selective Estrogen Receptor Modulators.
10. Current Regulations on Approval, criteria to ban and the regulatory body imposing ban on FDCs in India.

III. Reasoning Out:

(4 x 5 = 20)

1. Informed Consent versus Patient Information Sheet.
2. Orphan drugs – New definition, challenges in development.
3. Limitation of Surrogate end points in clinical trials with examples.
4. Signal Review Panel.
