

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

[M.PHARM 0823]

**AUGUST 2023
(APRIL 2023 EXAM SESSION)**

Sub. Code: 3006

**M.PHARMACY DEGREE EXAMINATION
SEMESTER - II (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER II – REGULATORY ASPECTS OF HERBAL & BIOLOGICALS**

Q.P. Code: 263006

Time : Three hours

Answer ALL Questions

Maximum : 75 Marks

I. Elaborate on:

(2 x 20 = 40)

1. Explain the process of BLA submission and approval in the US.
2. Explain regulatory guidelines for blood and its components including blood products in India.

II. Write notes on:

(7 x 5 = 35)

1. Write the GMP requirements for biologics in India.
2. Write about the advertising and labeling aspects of biologics in EU.
3. Write about the TSE/BSE evaluation.
4. Pharmacovigilance for vaccines in India.
5. United States regulations and guidelines for herbal medicine.
6. Legislative guidelines for herbal medicine in India.
7. Explain the safety and packaging system of herbal products in US.
