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

[M.PHARM 1223] DECEMBER 2023 Sub. Code: 3005
(OCTOBER 2023 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - II (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER I – REGULATORY ASPECTS OF DRUGS & COSMETICS

Q.P. Code: 263005

Time : Three hours **Answer ALL Questions** **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Explain the regulatory considerations for manufacture, packaging and labeling of pharmaceuticals in USA.

2. Discuss the regulatory requirements for registration of drugs and post approval requirements in WHO through prequalification programme.

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

1. Drug Master File (DMF) in US.
2. Hatch Waxman act and orange book.
3. Import and regulation for import of cosmetics in Australia.
4. Certificate of pharmaceutical product for Egypt and Nigeria.
5. Requirements for registration of drugs in China.
6. Regulatory committee in ASEAN and SADC.
7. Legislation and regulations for distribution and sale of cosmetics in Brazil.

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