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

[M.PHARM 0524] MAY 2024 Sub. Code: 2934
(APRIL 2024 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New regulations 2016)
PHARMACEUTICS - MPH
PAPER IV – REGULATORY AFFAIR

Q.P. Code: 262934

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

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

1. Discuss in detail the steps involved in Abbreviated New Drug regulatory approval process.

2. Explain ICH guidelines with respect to quality, safety and efficacy.

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

1. Write the components of drug master file.
2. Mention the specifications for five different types of USP dissolution apparatus.
3. Regulations involved in Investigational Medical Product Dossier.
4. Regulatory approval procedure for biologics.
5. Write the importance of post marketing surveillance.
6. Investigational brochure.
7. Health Insurance portability and accountability act.

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