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

[LQ 0121] JANUARY 2021 Sub. Code: 2934

(APRIL 2020 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION

SEMESTER-I (PCI New regulations 2016)

PHARMACEUTICS – MPH

PAPER IV – REGULATORY AFFAIRS

Q.P. Code : 262934

Time : Three hours Answer ALL Questions Maximum : 75 Marks

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

1. Describe the outsourcing protocol for the bioavailability and bioequivalence studies to contract research organization.

2. Discuss the drug approval submission process for investigational New Drug Application and New Drug Application.

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

1. Labeling review process in ANDA.
2. Regulatory process approval for Active Pharmaceutical Ingredient.
3. Investigational Medicinal Product dossier.
4. International Conference on Harmonization Efficacy Guideline.
5. Informed consent process.
6. Pharmacovigilance in safety monitoring.
7. Waivers of *In vivo* bioequivalence requirements.

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