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

[LP 934] NOVEMBER 2019 **Sub. Code: 2934**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
BRANCH I – PHARMACEUTICS – MPH
PAPER IV – REGULATORY AFFAIRS

Q.P. Code : 262934

Time : Three hours **Maximum : 75 Marks**

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

1. Explain in detail the various stages involved in FDA's new drug approval process.

2. What are Clinical trials? Explain the regulatory guidelines of the documentation, clinical study design with respect to various phases involved in clinical trials.

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

1. What is considered protected health information under HIPAA?
2. Electronic common technical document (eCTD).
3. Importance of *Invitro* drug characterization.
4. Generic drug user fee amendments (GDUFA).
5. Master formula record.
6. Objectives of CDER.
7. Guidelines of ICH – Q, S.

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