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

[LO 934] MAY 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. Give an account of outsourcing bioavailability and bioequivalence studies to contract research organization.

2. Discuss the following:
   a) NDA regulatory approval process.
   b) Active pharmaceutical ingredients and its specifications.

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

1. Post market surveillance.
2. Regulatory requirements of MHRA.
3. Investigator brochure.
4. HIPAA and its significance in clinical trials.
5. Regulatory requirement for product approval of biological products.
6. Independent ethics committee formulation and its working procedures.
7. Safety monitoring in clinical trials.

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