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

[M.PHARM 0922] **SEPTEMBER 2022** **Sub. Code: 2934**
(APRIL 2022 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. What are the Regulation for Combination Products and Medical devices?

2. Enumerate the regulatory submission protocol for Investigational New Drug and New Drug Application.

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

1. Specify the different codes used in code of federal regulations.
2. State the regulatory requirements for Active Pharmaceutical Ingredient.
3. Write the components of common technical document.
4. Describe the procedure involved in informed consent process.
5. Discuss the role of pharmacovigilance in safety monitoring.
6. Write the factors affecting *in vitro* drug product dissolution.
7. Mention the parameters in chemistry manufacturing control.

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