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

[BPHARM 0422] **APRIL 2022** **Sub. Code: 2080**
(SEPTEMBER 2021 SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)

PCI Regulation 2017 SEMESTER VIII
PAPER IV- PHARMACEUTICAL REGULATORY SCIENCES
Q.P. Code: 562080

Time: Three Hours **Maximum :75 marks**

I. Elaborate on: Answer any TWO questions. (2 x 10 = 20)

1. Explain the approval process of timeline involved in Investigational New Drug.
2. Explain the procedure for export of pharmaceutical products.
3. Explain the design in developing clinical trial protocols.

II. Write notes on: Answer any SEVEN questions. (7 x 5 = 35)

1. Explain the roles and responsibilities of the regulatory authority.
2. Explain the Orange Book features.
3. Explain the informed consent process & procedure involved in clinical trials.
4. Explain the Drug Master File.
5. Explain the Common Technical Document.
6. Explain the approval process for implementing the changes to an approved NDA.
7. Explain the regulatory authorities of Australia.
8. Explain the preclinical studies involved in drug discovery.
9. Explain the concept of generics & Generic drug product development.

III. Short answers on: Answer ALL questions. (10 x 2 = 20)

1. Phase 3 clinical trial.
2. CDSCO.
3. WHO.
4. Regulatory authorities of Canada.
5. Purple Book.
6. Phase 2 clinical trial.
7. EMA.
8. Functions of Ethics committee.
9. Investigational Product.
10. Three arm study.

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