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

[B.PHARM 0823] AUGUST 2023 Sub. Code: 2080
(MARCH 2023 EXAM SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 - SEMESTER VIII
PAPER X - PHARMACEUTICAL REGULATORY SCIENCE

Q.P. Code: 562080

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

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

1. Explain the stages of drug discovery.
2. Explain the GCP obligations of investigators sponsors and monitors.
3. Explain the Code of Federal Regulatory and purple book.

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

1. Explain the generic drug product development.
2. Illustrate the pre-clinical studies.
3. Explain the timelines involved in Investigational New Drug (IND).
4. Explain the Abbreviated New Drug Application (ANDA).
5. Explain the overview of regulatory authorities of India.
6. Explain the procedure for export of pharmaceutical products.
7. Explain the Electronic Common Technical Document.
8. Explain Orange Book.
9. Elaborate on Federal Register.

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

1. Regulatory authorities of Canada.
2. Generic drug.
3. EMA.
4. Timelines involved in NDA.
5. Drug Master File.
6. Pharmacovigilance.
7. Institutional Review Board.
8. GCP.
9. Name the regulatory authority of Australia and USA.
10. Clinical Trials.

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