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

[B.PHARM 0323] MARCH 2023 Sub. Code: 2080
(SEPTEMBER 2022 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 in detail about stages involved in drug discovery.
2. Discuss about Pharmaceutical policy 2002.
3. Explain about CTD and e CTD.

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

1. Write a note on organisation of ASEAN CTD format.
2. Compare innovator and generics.
3. Explain in detail about functions of CDSCO.
4. Write a note on procedure for obtaining No objection Certificate (NOC) for export of unapproved / approved new drugs / banned drugs.
5. Discuss obligations of investigators, sponsors and monitors.
6. Brief about the guidance documents for NDAs.
7. Explain the role of EMA and PDMA.
8. Write a note overview of regulatory authorities of USA.
9. Write about managing and monitoring clinical trials.

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

1. Define bioinformatics.
2. What is New drug Development?
3. What is placebo?
4. What is a 505(b)(2) application?
5. What do you mean by draft pharmaceutical policy 2006?
6. Define CTA.
7. Define Pharmacovigilance.
8. Define Orange book.
9. What is an investigational new drug (IND) application?
10. Name any five regulatory agencies and organisations established in countries.

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