

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

[B.PHARM 1223]

**DECEMBER 2023
(SEPTEMBER 2023 EXAM SESSION)**

Sub. Code: 2080

**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. Define Investigational New Drug. Explain about its types and category.
2. Write a note on role and responsibilities of lead investigator and Node principal investigator.
3. Explain in detail about regulatory bodies govern the pharmaceutical sector in India.

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

1. Write a brief note on resources of IND applications.
2. Explain the changes to an approved ANDA and assessing the effect of manufacturing changes.
3. Write a note on advance technologies in drug discovery.
4. Explain in detail about drug price control order (DPCO) 1995.
5. Write a note overview of regulatory authorities of Japan.
6. Write a note on module and benefits of e CTD.
7. Explain about institutional review board / Independent ethics committees (IECS).
8. Describe the importance of Hatch Waxman act.
9. Discuss in detail the contents of orange book.

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

1. Define regulatory affairs.
2. What is generic drug product?
3. What is marketing authorization application?
4. What is 180 day exclusivity?
5. What do you mean by good clinical practice?
6. Which ANDA process is applicable for 21 CFR Part 320?
7. Give the full form of following abbreviated terms: a) QMS, b) GPSP.
8. What is branded drug?
9. Give the task of post marketing drug safety unity.
10. Write about e CTD management software.
