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

[B.PHARM 0524] **MAY 2024** **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. Explain the stages in development of new drug.
2. Discuss the application and approval process for Abbreviated New Drug Application (ANDA).
3. Explain Drug regulatory agencies in India.

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

1. Explain the various steps involved in generic procedure development.
2. Explain various phased of clinical trials.
3. Write a note on CDSCO.
4. Explain the regulatory authorities of European Union.
5. Discuss briefly the open part and closed part of DMF.
6. Enlist the things that FDA regulates directly and indirectly.
7. Explain the code of federal regulatory.
8. Explain in details about the orange book and the purple book.
9. Explain the function of IRB (Institutional Review board).

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

1. Target validation.
2. Types of shipping bill.
3. Enlist the modules of CTD (Common Technical Document).
4. Process of DMF (Drug Master File) review.
5. Export generic product.
6. Name the regulatory authorities of US and Australia.
7. Types of DMF.
8. Exclusion criteria in clinical trials.
9. Non-clinical trials.
10. Define regulatory affairs.

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