

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

[B.PHARM 1223]

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

Sub. Code: 2089

**B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 - SEMESTER VIII
PAPER VIII - PHARMACEUTICAL PRODUCT DEVELOPMENT
Q.P. Code: 562089**

Time: Three hours

Maximum: 75 Marks

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

1. Define optimization techniques. Elaborate in detail about various optimization technique with suitable examples.
2. Define and explain the role of suspending and emulsifying agents in formation of stable suspension and emulsion.
3. Write in detail about the preformulation involved in pharmaceutical product development.

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

1. Discuss about the quality control testing for dosage forms.
2. Write a note on cyclodextrins.
3. Explain in detail about the excipients used in coating with their roles.
4. Discuss the methods of preparing directly compressed vehicles.
5. Enlist and discuss various propellants used in aerosols.
6. Detailed note on various applications of QbD in product development with suitable examples.
7. Elaborate upon functions of pharmaceutical packaging.
8. What is the use of rubber and elastomer rubber in pharmaceutical packaging?
9. Discuss about quality control tests for plastic containers in parenteral and non-parenteral use.

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

1. Any four objectives of pharmaceutical product development.
2. Define stability indicating assay method.
3. Explain the role of alcohol as solvents.
4. Examples of suspending agents.
5. Define lubricants and sorbents.
6. What are anti-adherents?
7. What is confounding?
8. Any 4 optimization benefits for industry.
9. Types of packaging.
10. Explain compliance.
