

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

**[B.PHARM 0323]**

**MARCH 2023  
(SEPTEMBER 2022 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 and explain about the selection of packaging materials.
2. Define QbD. State the tools of QbD with explanations.
3. Detailed account on directly compressible vehicles.

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

1. What are the marketing strategies in pharmaceutical product development?
2. Write a note on PEG.
3. Regulatory requirements for quality control testing of pharmaceutical products.
4. What are prescribed products and OTC products?
5. What is sorbitol? How it is prepared? Write about its properties.
6. What are suspending agents? Write their ideal properties and various functions.
7. Discuss advanced excipients and their applications in NDDS.
8. Classification of optimization techniques.
9. Write a note on audit inspection.

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

1. Evaluation test for granules.
2. Any four objectives of pharmaceutical product development.
3. What are non-ionic surfactants?
4. Define gelling agents.
5. What are coating materials?
6. Advantages of binders.
7. What is multilevel and multiobjective optimization?
8. Define factors and trials.
9. What is device packaging?
10. Functions of pharmaceutical packaging.

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