

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

**[B.PHARM 0823]**

**AUGUST 2023  
(MARCH 2023 EXAM SESSION)**

**Sub. Code: 2067**

**B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)  
PCI Regulation 2017 – SEMESTER VI  
PAPER VI – QUALITY ASSURANCE**

*Q.P. Code: 562067*

**Time: Three hours**

**Maximum: 75 Marks**

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

1. Describe the design, plant layout, maintenance and sanitation of premises.
2. Explain good laboratory practices.
3. Discuss about quality by design.

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

1. Discuss the calibration of pH meter.
2. Write the quality control tests for plastic containers.
3. Discuss about good warehousing practices.
4. Write a note on ICH stability testing guidelines.
5. Explain about quality documentation.
6. Write a note on personnel responsibilities.
7. Discuss about total quality management.
8. Explain about recalling and waste disposal.
9. Discuss about maintenance of equipment.

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

1. Quality control.
2. Hydrolytic resistance test for glass containers.
3. Distribution record.
4. User requirement specification.
5. Factory acceptance test.
6. Process validation.
7. Quality audit.
8. Q-series guidelines.
9. Control of contamination.
10. ISO 14000.

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