

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

[BPHARM 0122]

**JANUARY 2022
(MARCH 2021 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, construction and plant layout of Pharmaceutical Industry.
2. How complaints should be handled according to the GMP provisions? Elaborate recalling and handling of return goods.
3. What are the general principles of analytical method development? Compare accuracy and precision of LOD and LOQ with reference to ICH guidelines.

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

1. QSEM with special emphasis on Q-series guidelines.
2. Compare calibration, qualification and validation.
3. Testing facilities operation and disqualifying of testing facilities.
4. Explain quality Audit.
5. Compare the concept of QA and QC as per GMP.
6. What are the general provisions of good laboratory practices?
7. How do you conduct a nonclinical laboratory study?
8. Quality control test for secondary packing materials.
9. Good warehousing practices.

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

1. Concept of quality assurance.
2. Elements of TQM.
3. Personal records.
4. Control of contamination.
5. Quality review.
6. Overview of Qbd.
7. Evaluation of complaints.
8. Distribution records.
9. Materials management.
10. Calibration of pH meter.
