

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

[BPHARM 0321]

MARCH 2021

Sub. Code: 2067

(SEPTEMBER 2020 EXAM SESSION)

B. PHARMACY DEGREE EXAMINATION

PCI Regulation 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. Discuss the concept Quality by design. What are various elements and tools required for the same?
2. Discuss the concept, general provisions and protocols of GLP with reference to a nonclinical laboratory study.
3. What is good warehousing practices? Describe briefly material management in a warehouse.

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

1. Elements and philosophies of total quality management.
2. General principles of analytical method validation.
3. Brief overview of QSEM.
4. Purchase specifications and maintenance of stores for raw materials.
5. Quality control test for rubber closures.
6. Plant layout of pharmaceutical industry.
7. Quality review and quality documentation.
8. Batch formula records.
9. Benefits and elements of ISO 9000 and ISO 14000.

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

1. Principles of NABL Accreditation.
2. Master formula records.
3. Purpose of ICH guidelines.
4. Concept of GMP.
5. Quality audit.
6. Handling of return good.
7. Records and reports.
8. SOP.
9. Purchase specifications.
10. Validation master plan.
