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

[BPHARM 0921] **SEPTEMBER 2021** **Sub. Code: 2067**

(SEPTEMBER 2020 EXAM SESSION)

B. PHARMACY DEGREE EXAMINATION
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. What is the concept of TQM, describe in details various elements required for management of quality in pharmaceutical industry.
2. Explain the quality control tests for containers, rubber closures and secondary packing materials.
3. Compare calibration, qualification and validation. How do you prepare validation master plan? Describe calibration of UV-visible spectrophotometer.

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

1. ICH stability testing guidelines.
2. Describe the principle of NABL accreditations.
3. Write details on GMP with respect to sanitation and hygiene.
4. Signification of equipment validation.
5. GLP for test and control articles.
6. Disqualification of testing facilities.
7. Complaints and evaluation of complaints.
8. Master formula record.
9. General principles of analytical method validation.

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

1. SOP.
2. Batch formula records.
3. Waste disposal.
4. Concept of quality control.
5. Non clinical laboratory.
6. Tools and elements of Qbd.
7. Good warehousing practice.
8. Benefits of ISO 14000.
9. Quality managements.
10. General provision of GLP.

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