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

[BPHARM 1022] OCTOBER 2022 Sub. Code: 2073
(MARCH 2022 EXAM SESSION)

B. PHARMACY DEGREE EXAMINATION
PCI Regulation SEMESTER - VII
PAPER II – INDUSTRIAL PHARMACY
Q.P. Code : 562073

Time: Three hours **Maximum: 75 Marks**

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

1. What do you mean by pilot plant and scale up? Discuss the general considerations in pilot plant scale up technique.
2. Define Investigational New Drug (IND). Discuss the content and format of Investigational New Drug Application.
3. Discuss Total Quality Management and its importance.

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

1. Central Drug Standard Control Organization.
2. Platform technology.
3. Technology Transfer agencies in India.
4. Historical overview of Regulatory Affairs.
5. Non-clinical Drug development.
6. ISO 14000.
7. Regulatory requirements and approval procedures for new drugs.
8. Pilot plant scale up considerations of liquid orals.
9. Roles and responsibilities of Regulatory Affairs department.

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

1. What is SUPAC?
2. Define Quality Risk Management and give its principle.
3. What is meant by Drug Master File?
4. What is confidentiality agreement in Technology Transfer?
5. What is Abbreviated New Drug Application?
6. Define Clinical Research. What are the types of Clinical Research?
7. The United States Food and Drug Administration (USFDA).
8. Application of biostatistics in pharmaceutical product development.
9. COPP.
10. What is Six Sigma Concept?

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