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

[BPHARM 1221] DECEMBER 2021 Sub. Code: 2073
(MARCH 2021 EXAM SESSION)

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

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

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

1. Discuss general considerations of Investigational new drug application.
2. Discuss about documentation, premises and equipments for TT as per WHO guidelines.
3. What is full form of SUPAC guideline? Discuss its application and significance.

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

1. Write a note on clinical research protocol.
2. Discuss total quality management.
3. Biostatistics in Pharmaceutical product development.
4. Regulatory requirement of bioequivalence studies.
5. Describe the clinical trial protocol.
6. Explain the procedure for pilot plant scale-up for liquid orals.
7. Explain technology transfer form R & D to production as per WHO guidelines.
8. Organizational structure of regulatory affairs.
9. Explain in brief concept of quality by design.

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

1. CDSCO.
2. Define finished pharmaceutical product.
3. Define Six sigma.
4. TT agencies in India.
5. COPP.
6. State licensing Authority.
7. What is quality control?
8. What is Good Manufacturing Practices?
9. What is qualification and validation?
10. Why to conduct pilot plant studies?

****

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

[BPHARM 0522] **MAY 2022** **Sub. Code: 2073**

(SEPTEMBER 2021 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. Explain the procedure for pilot plant scale-up semisolid dosage form
2. Define technology transfer .what is sending unit and receiving unit? Write the WHO Guidelines for technology transfer.
3. What are the regulatory requirements and approval procedures for new drugs?

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

1. Write briefly on the Technology Transfer (TT) process for finished product
2. Write a note on Drug Master Files
3. Discuss NDA regulatory approval process with suitable examples
4. Write a short note on Investigator's Brochure (IB).
5. Write a short note on post marketing surveillance
6. Write a short note on management of clinical studies
7. SUPAC Guidelines.
8. Discuss the role and responsibility of regulatory affairs.
9. Analytical method Technology Transfer.

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

1. What are BE & BA studies?
2. What are the advantages of pilot plant studies?
3. Advantages of technology transfer.
4. What is the purpose of pre-clinical testing?
5. What is Good Laboratory Practices?
6. National Research Development Corporation (NRDC).
7. What do you mean by ANDA?
8. Define clinical research.
9. Quality by Design (QbD)
10. Define In-process control.

****

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?

****

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

[B.PHARM 0323] MARCH 2023 Sub. Code: 2073
(SEPTEMBER 2022 EXAM SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 - SEMESTER - VII
PAPER II – INDUSTRIAL PHARMACY – II

Q.P. Code: 562073

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

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

1. Discuss the pilot plant scale up considerations for solids.
2. What is Technology Transfer? Explain Technology Transfer protocol.
3. Discuss about New Drug Application and Investigational New Drug Application.

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

1. SUPAC guidelines.
2. Responsibilities of Regulatory affairs professional.
3. Technology Transfer agencies in India.
4. Investigator's brochure.
5. Clinical Research and its types.
6. ISO 9000 series of quality standards.
7. Define bioequivalence studies and explain it.
8. Certificate of Pharmaceutical Product.
9. Organization and responsibilities of Central Drug Standard Control Organization.

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

1. Standard Operating Procedure.
2. Give the significance of Drug Master File.
3. Give the principle of Quality Risk Management.
4. Technology Transfer related documentation.
5. What is Non-clinical drug development?
6. What do you mean by Six Sigma concept?
7. Application of biostatistics in pharmaceutical product development.
8. What is meant by NABL certification?
9. Responsibilities of State Licensing Authorities.
10. What is Clinical Trial? Mention the phases of a clinical trial.

****