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?

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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.

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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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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.

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

[B.PHARM 0823] AUGUST 2023 Sub. Code: 2073
(MARCH 2023 EXAM SESSION)

B. PHARMACY DEGREE EXAMINATION
PCI Regulation 2017 - 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. Define Pilot plant scale. Discuss the objectives, personnel, space, raw material requirements and preparation of Master Manufacturing Record.
2. Describe in detail about the role and responsibility of regulatory affairs department.
3. Discuss about the principles, advantages, needs and scope of NABL.

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

1. SUPAC guidelines.
2. Approved regulatory bodies & agencies.
3. Quality Risk Management.
4. Drug Development Teams.
5. Non clinical drug development.
6. Total quality Management.
7. Note on GLP.
8. Central license approving authority.
9. Requirements for permission of NDA.

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

1. CDSCO.
2. DMF – Drug Master File.
3. Where clinical studies are conducted?
4. ANDA.
5. Concepts of Quality.
6. DTAB.
7. Types of COPP (Certificate Of Pharmaceutical Products).
8. Phases for clinical trials.
9. USFDA.
10. Technology Transfer Protocol.

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

[B.PHARM 1223] DECEMBER 2023 Sub. Code: 2073
(SEPTEMBER 2023 EXAM SESSION)

B. PHARMACY DEGREE EXAMINATION
PCI Regulation 2017 - 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. Enumerate the agencies for Technology Transfer in India.
2. Define Certificate Of Pharmaceutical Products (COPP). Discuss the purpose, scope, importance and functions.
3. Define Investigational New Drug (IND). Classify them, mention its types of application and layout chart for IND application.

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

1. Pilot plant scale up consideration for liquid orals.
2. SUPAC.
3. Write note on Analytical Method Transfer.
4. Investigator's Brochure.
5. Bio equivalence studies.
6. Six Sigma concepts.
7. Scope of pharmaceutical QMS.
8. Organizational structure of CDSCO.
9. Drug Testing Laboratories.

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

1. Expand – BCIL, NRDC.
2. CDSCO.
3. Standard Operating Procedure.
4. Change Control.
5. Drug Master File.
6. What is NABL?
7. QbD.
8. WHO.
9. ISO 9000.
10. New Drug Application.

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

[B.PHARM 0524] **MAY 2024** **Sub. Code: 2073**

B. PHARMACY DEGREE EXAMINATION
PCI Regulation 2017 - 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. Enumerate the Scale Up Post Approval Changes (SUPAC guidelines).
2. Explain the following:
   (a) Analytical method transfer.
   (b) Technology Transfer related documents.
   (c) WHO guidelines for Technology Transfer.
3. What is CDSCO? Discuss its organizational structure, functions and responsibilities.

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

1. Pilot plant scale up consideration for semisolids.
2. Write note on MoUs.
3. Agencies for Technology Transfer in India.
4. Clinical Research Protocols.
5. Role of regulatory affairs professionals.
6. ICH guidelines of QMS.
7. Requirement of ISO 9000.
8. State drug Licensing authority.
9. Process to apply for COPP.

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

1. Master Manufacturing Record.
2. Expand – TIFAC, NRDC.
3. DCGI.
4. API.
5. Change control.
6. Define Quality Management Systems.
7. GLP.
8. Drug Testing Laboratories.
9. Who conducts clinical studies?
10. Regulatory requirements for drug approval.

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

[B.PHARM 1024] OCTOBER 2024 Sub. Code: 2073
(SEPTEMBER 2024 EXAM SESSION)

B. PHARMACY DEGREE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 - 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 is a significance of pilot plant scale up? Give examples.
2. Explain the details of central drugs laboratory and functions.
3. Write the basic principles and requirements of ISO 9000 series in detail.

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

1. Technology Transfer Protocol.
2. Write about various drug regulatory agencies.
3. Explain the principles of ISO 14000 series.
4. Briefly discuss master formula record and its importance.
5. Write about six sigma concepts.
6. Write a note on state licensing authorities.
7. Write a note on non-clinical drug development process.
8. What are the uses of platform technology?
9. Discuss the different phase of clinical trial.

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

1. What are the goals of technology transfer?
2. Define quality risk management.
3. What is Standard Operating Procedure?
4. Define Pilot plant and scale up.
5. What is validation protocol and validation report?
6. TT related documentation.
7. Key components of total quality management.
8. What is installation qualification?
9. NABL, GLP.
10. World Health Organization (WHO).

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

[B.PHARM 0325] **MARCH 2025** **Sub. Code: 2073**

B. PHARMACY DEGREE (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. Describe the steps involved in the pilot plant scale up techniques for the development of semisolid dosage forms with relevant documentation.
2. Discuss the WHO guidelines followed for Technology Transfer from R & D to Production.
3. Discuss general considerations related with Investigational new drug application (INDA).

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

1. SUPAC guidelines.
2. Explain approved regulatory bodies and agencies for Technology Transfer.
3. Drug development Team.
4. Write a note on clinical research protocol.
5. Biostatistics in Pharmaceutical product development.
6. Total Quality Management (TQM).
7. Describe Quality by Design (QbD).
8. What are the responsibilities of CDSCO?
9. Regulatory requirements for approval of new drugs.

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

1. Significance of pilot plant studies.
2. Quality risk management.
3. National Research Development Corporation (NRDC).
4. Define NDA.
5. Steps of drug development process.
6. What is BE studies?
7. Explain COPP.
8. Define MoU.
9. List out the different modules of CTD.
10. Components of an investigator’s brochure.

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

[B.PHARM 0925] **SEPTEMBER 2025** **Sub. Code: 2073**

B. PHARMACY DEGREE (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. Explain about Quality by design (QbD).
2. Pilot plant scale up consideration for solids.
3. Quality Risk Management (QRM).

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

1. Out of specification (OOS).
2. Principles of ISO 9000 series.
3. Bioequivalence studies.
4. Different types of platform technology.
5. Qualification and validation.
6. Technology transfer protocol.
7. Management of clinical studies.
8. Confidentiality agreements in technology transfer.
9. Regulatory requirements for approval of new drugs.

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

1. Need for obtaining ISO 9000 certification.
2. Types of Investigational New Drug (IND) applications.
3. Critical control point.
4. Receiving unit (RU) and Sending unit (SU).
5. Validation Master Plan (VPM).
6. Give name of regulatory authorities of India, UK, Australia, USA.
7. Phase II clinical trials.
8. Six Sigma Concepts.
9. Basic elements of TQM Total Quality Management.
10. Members of FDA Investigational New drug Review team.

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