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

[BPHARM0422] APRIL 2022 Sub. Code: 2089
(SEPTEMBER 2021 SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 SEMESTER VIII
PAPER XIII - PHARMACEUTICAL PRODUCT DEVELOPMENT
Q.P. Code: 562089

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

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

1. Discuss about the regulations related to different types of dosage forms.
2. Briefly write about optimization by factorial designs.
3. Write about the glass packaging material for pharmaceutical product development.

II. Short answers on: Answer any SEVEN questions. (7 x 5 = 35)

1. Advantages and disadvantages of plastic containers.
2. Solvents and solubilizers.
3. Suspending agents.
4. Semisolid excipients.
5. Capsule excipients.
6. Excipients in aerosols products.
7. Quality control testing of capsule.
8. Terminology of packaging material.
9. Objectives of pharmaceutical product development.

III. Write notes on: Answer ALL questions. (10 x 2 = 20)

1. Advantages of glass container.
2. Tertiary packaging.
3. Emulsifying agents.
4. Polyethylene glycol.
5. Types of problems in optimization.
6. Mention the elements of quality by design.
7. Classification non-ionic surfactant.
8. Systemic optimization techniques.
9. Application of optimization.
10. Pharmaceutical excipients.

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

[BPHARM 1022] OCTOBER 2022 Sub. Code: 2089
(MARCH 2022 SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 - SEMESTER VIII
PAPER XIII - PHARMACEUTICAL PRODUCT DEVELOPMENT
Q.P. Code: 562089

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

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

1. Discuss about the various excipients in product development of tablets and capsules..
2. Briefly write about the application of optimization.
3. Write about the plastic packaging material for pharmaceutical product development.

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

1. Types of pharmaceutical packaging.
2. Non ionic surfactant and their applications.
3. Emulsifying agents.
4. Describe various solvent used in development of pharmaceutical products.
5. Directly compressible vehicles.
6. Excipients for formulation of novel drug delivery system.
7. Coat materials.
8. Properties of packaging material.
9. Regulations at formulation development.

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

1. Types of glass containers.
2. Metals containers.
3. Sorbital.
4. Examples of semisolid excipients.
5. Statistical design of optimization.
6. Advantages of quality by design.
7. Water soluble organic solvents.
8. Numerical optimization techniques.
9. Fractional factorial design.
10. Pharmaceutical product development.

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

[B.PHARM 0323] MARCH 2023 Sub. Code: 2089
(SEPTEMBER 2022 EXAM SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 - SEMESTER VIII
PAPER VIII - PHARMACEUTICAL PRODUCT DEVELOPMENT
Q.P. Code: 562089

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

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

1. Define and explain about the selection of packaging materials.
2. Define QbD. State the tools of QbD with explanations.
3. Detailed account on directly compressible vehicles.

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

1. What are the marketing strategies in pharmaceutical product development?
2. Write a note on PEG.
3. Regulatory requirements for quality control testing of pharmaceutical products.
4. What are prescribed products and OTC products?
5. What is sorbitol? How it is prepared? Write about is properties.
6. What are suspending agents? Write their ideal properties and various functions.
7. Discuss advanced excipients and their applications in NDDS.
8. Classification of optimization techniques.
9. Write a note on audit inspection.

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

1. Evaluation test for granules.
2. Any four objectives of pharmaceutical product development.
3. What are non-ionic surfactants?
4. Define gelling agents.
5. What are coating materials?
6. Advantages of binders.
7. What is multilevel and multiobjective optimization?
8. Define factors and trials.
9. What is device packaging?
10. Functions of pharmaceutical packaging.

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

[B.PHARM 0823] AUGUST 2023 Sub. Code: 2089
(MARCH 2023 EXAM SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 - SEMESTER VIII
PAPER VIII - PHARMACEUTICAL PRODUCT DEVELOPMENT

Q.P. Code: 562089

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

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

1. Discuss about the pharmaceutical product development.
2. Briefly write about the optimization techniques in product development.
3. Write about the quality control testing of packaging material.

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

1. Advantages and disadvantages of glass containers.
2. Cyclodextrine and their applications.
3. Polyethylene glycols and sorbital.
4. Elaborate upon use of solubilizers in product development.
5. Tablet excipients.
6. Excipients in parenteral products.
7. Quality control testing of tablets.
8. Ideal requirement of packaging materials.
9. Stability assessment.

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

1. Advantages of plastic containers.
2. Secondary packaging.
3. Applications of surfactant and examples.
4. Suspending agents.
5. Types of variable optimization.
6. Objectives of quality by design.
7. Water insoluble organic solvents.
8. Full factional design.
9. Pharmaceutical excipient - II.
10. Classification of emulsifying agents.

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

[B.PHARM 1223] DECEMBER 2023 Sub. Code: 2089
(SEPTEMBER 2023 EXAM SESSION)

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 - SEMESTER VIII
PAPER VIII - PHARMACEUTICAL PRODUCT DEVELOPMENT
Q.P. Code: 562089

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

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

1. Define optimization techniques. Elaborate in detail about various optimization technique with suitable examples.
2. Define and explain the role of suspending and emulsifying agents in formation of stable suspension and emulsion.
3. Write in detail about the preformulation involved in pharmaceutical product development.

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

1. Discuss about the quality control testing for dosage forms.
2. Write a note on cyclodextrins.
3. Explain in detail about the excipients used in coating with their roles.
4. Discuss the methods of preparing directly compressed vehicles.
5. Enlist and discuss various propellants used in aerosols.
6. Detailed note on various applications of QbD in product development with suitable examples.
7. Elaborate upon functions of pharmaceutical packaging.
8. What is the use of rubber and elastomer rubber in pharmaceutical packaging?
9. Discuss about quality control tests for plastic containers in parenteral and non-parenteral use.

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

1. Any four objectives of pharmaceutical product development.
2. Define stability indicating assay method.
3. Explain the role of alcohol as solvents.
4. Examples of suspending agents.
5. Define lubricants and sorbents.
6. What are anti-adherents?
7. What is confounding?
8. Any 4 optimization benefits for industry.
9. Types of packaging.
10. Explain compliance.

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

[B.PHARM 0524] **MAY 2024** **Sub. Code: 2089**

B.PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 - SEMESTER VIII
PAPER VIII - PHARMACEUTICAL PRODUCT DEVELOPMENT

Q.P. Code: 562089

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

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

1. Discuss about QbD (Quality by design) and its application in Pharmaceutical vaccine production.
2. Write briefly about tablets Excipients.
3. Discuss about stability assessment in pharmaceutical product development.

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

1. Types of factorial designs.
2. Emulsifying agents.
3. Semi solid excipients.
4. Advantages and disadvantages of Glass container.
5. Types of packaging.
6. Polyethylene glycol.
7. Film coating materials.
8. Excipients in microspheres.
9. Non-ionic surfactant.

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

1. Types of packaging materials.
2. Advantages of metal containers.
3. Define pre-formulation.
4. Types of suspending agents.
5. Examples for semi solid Excipients.
6. Evaluation test for closures.
7. Directly compressible vehicles.
8. Capsules Excipients.
9. Define optimization.
10. What is meant by directly compressible vehicles?

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

[B.PHARM 1024] OCTOBER 2024 Sub. Code: 2089
(SEPTEMBER 2024 EXAM SESSION)

B. PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 - SEMESTER VIII
PAPER VIII - PHARMACEUTICAL PRODUCT DEVELOPMENT

Q.P. Code: 562089

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

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

1. Discuss about factorial design and its types.
2. Pre-formulation studies in product development.
3. Excipients used in the tablet preparation.

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

1. Importance of stability testing.
2. Characteristics of packaging materials.
3. Sorbitol.
4. Semi solid excipients.
5. Quality control test for parenteral preparation.
6. Quality control test for Plastic containers.
7. Advantages and disadvantages of optimization techniques.
8. Objectives of QbD (Quality by Design).
9. Excipients in parenteral preparation.

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

1. Advantages of plastic containers.
2. Examples for Non-ionic Surfactants.
3. Define - Excipients.
4. Types of solvents.
5. Uses of polyethylene glycol.
6. Benefits of quality by design (QbD).
7. Raw materials used for packaging.
8. Define – aerosol.
9. Different types of tablet coating.
10. Define Optimization techniques.

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

[B.PHARM 0925] SEPTEMBER 2025 Sub. Code: 2089

B. PHARMACY DEGREE COURSE (SEMESTER EXAMINATIONS)
PCI Regulation 2017 - SEMESTER VIII
PAPER VIII - PHARMACEUTICAL PRODUCT DEVELOPMENT

Q.P. Code: 562089

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

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

1. Classify emulsifying agents with examples and discuss on the various applications of non-ionic surfactants.
2. Write in detail about the regulations related to the stability assessment of pharmaceutical products.
3. Describe briefly the quality control testing of parenteral products.

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

1. Discuss in detail the different materials used in the development of aerosol container.
2. Types of suspending agents and their applications.
3. Quality control testing of plastic containers.
4. Discuss on the excipients used in the capsule development.
5. What is quality by design? Outline its significance in pharmaceutical product development.
6. Compare diluents and directly compressible vehicles.
7. Regulations related to the manufacturing of liquid orals.
8. Explain the various experimental designs studied during product development.
9. Elaborate on the preparation, properties and applications of sorbitol.

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

1. Give two examples for gelling agents.
2. Risk assessment tools.
3. Stress testing.
4. Di-Pac.
5. Bubble pack.
6. What does ICH QIF state?
7. Examples of permeation enhancers.
8. What are gas absorbers or desiccants?
9. Name any three super disintegrants.
10. Suppository bases.

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