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

[LL 933] NOVEMBER 2017 **Sub. Code: 2933**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
PHARMACEUTICS – MPH
PAPER III – MODERN PHARMACEUTICS

Q.P. Code : 262933

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

I. Elaborate on: **(2 x 20 = 40)**

1. Define pharmaceutical validation and write its scope and merits. Discuss the general guidelines for the validation and calibration of pharma equipments.

2. Discuss the objectives and policies of CGMP. Write the GMP requirements and layout of buildings, services, equipments, and their maintenance for solid dosage form products.

II. Write notes on: **(7 x 5 = 35)**

1. Higuchi and Peppas plot and its applications.
2. Evaluation of large volume parentrals.
3. Pharmacokinetic parameters.
4. Material and inventory management in pharma industry.
5. Distribution of forces during compression of tablets.
6. Total quality management.
7. Protocols of stability studies.

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

[LM 933] MAY 2018 **Sub. Code: 2933**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
PHARMACEUTICS – MPH
PAPER III – MODERN PHARMACEUTICS

Q.P. Code : 262933

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

I. Elaborate on: **(2 x 20 = 40)**

1. Give an account on plant requirement, manufacturing and evaluation of large volume parentrals.

2. Discuss the energy and force involvement in compression of tablets. Write a note on effect of particle size and moisture content on the tablet compression.

II. Write notes on: **(7 x 5 = 35)**

1. Stability testing protocols.
2. Types of validation.
3. Inventory management and sales forecasting.
4. Students ‘t’-test and its significance.
5. Factors influencing solubility.
6. Optimization techniques in pharmaceutical processing.
7. Concept of total quality management.

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

[LN 933] NOVEMBER 2018 **Sub. Code: 2933**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
PHARMACEUTICS – MPH
PAPER III – MODERN PHARMACEUTICS

Q.P. Code : 262933

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

I. Elaborate on: **(2 x 20 = 40)**

1. Define optimization. Explain elaborately about factorial designs and its application in pharmaceutical formulation.

2. Discuss in detail about preparation and stability of emulsion.

II. Write notes on: **(7 x 5 = 35)**

1. Response surface method.
2. Diffusion and dissolution parameters.
3. Management of handling and transportation of materials.
4. Accelerated stability testing.
5. ANOVA test.
6. Validation and calibration of master plan.
7. Different methods to determine drug-excipient interactions.

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

[LO 933] MAY 2019 **Sub. Code: 2933**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
BRANCH I – PHARMACEUTICS – MPH
PAPER III – MODERN PHARMACEUTICS

Q.P. Code : 262933

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

I. Elaborate on: **(2 x 20 = 40)**

1. Define stability. Explain elaborately about stability testing.
2. Discuss in detail about production management.

II. Write notes on: **(7 x 5 = 35)**

1. Consolidation parameters.
2. Calibration and validation of equipments.
3. Self micro-emulsifying drug delivery system.
4. Concept and parameters of optimization.
5. Performance qualification in pharmaceutical validation.
6. Methods used for enhancement of solubility of poorly water soluble drugs.
7. Layout of buildings in current good manufacturing practices.

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

[LP 933] NOVEMBER 2019 **Sub. Code: 2933**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
BRANCH I – PHARMACEUTICS – MPH
PAPER III – MODERN PHARMACEUTICS

Q.P. Code : 262933

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

I. Elaborate on: **(2 x 20 = 40)**

1. What is the importance of optimization? Classify and explain the different methods of optimization.

2. Discuss the preformulation studies for pharmaceutical formulations.

II. Write notes on: **(7 x 5 = 35)**

1. Add a note on similarity and differential factors.
2. Physics of tablet compression.
3. Explain the concept of Total quality management.
4. What are the key elements of validation Master plan?
5. Describe the spectroscopic techniques of analyses of drug-excipient interaction study.
6. Write the applications of factorial design in formulations.
7. What are the guidelines to be followed for production of User Requirements Specification (URS)?

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

[LQ 0121] JANUARY 2021 Sub. Code: 2933

(APRIL 2020 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION

SEMESTER-I (PCI New regulations 2016)

PHARMACEUTICS – MPH

PAPER III – MODERN PHARMACEUTICS

Q.P. Code : 262933

Time : Three hours **Answer ALL Questions** **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Discuss in detail types, composition, evaluation, advantages and limitations of pharmaceutical dispersions formulations.

2. Describe in detail validation process for manufacturing tablets.

II. Write notes on: **(7 x 5 = 35)**

1. Types of Process Validation.
2. Add a note on manufacturing process model for solid dosage form.
3. Describe Heckel plot for compaction of tablet.
4. Discuss GMP for equipment cleaning and maintenance.
5. Explain Physics of Tablet compression.
6. Discuss the concept of Optimization.
7. Sales forecasting technique.

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

[MPHARM 0921] SEPTEMBER 2021 Sub. Code: 2933
(OCTOBER 2020 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER-I (PCI New regulations 2016)
PHARMACEUTICS - MPH
PAPER III – MODERN PHARMACEUTICS
Q.P. Code : 262933

Time : Three hours **Answer ALL Questions** **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Write pharmaceutical validation, scope and its merits. Discuss the general guidelines for the validation and calibration of pharmaceutical equipments.

2. Discuss in detail the different methods to assess drug – excipient interaction.

II. Write notes on: **(7 x 5 = 35)**

1. Application of Heckel plot.
2. Discuss the objective and policies of cGMP.
3. Factorial designs.
4. Discuss about dissolution parameters.
5. Evaluation of large volume parenterals.
6. Give the planning to prepare budget and its control.
7. Physics of tablet compression.

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

[MPHARM 0122] JANUARY 2022 Sub. Code: 2933
(APRIL 2021 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER-I (PCI New regulations 2016)
PHARMACEUTICS - MPH
PAPER III – MODERN PHARMACEUTICS
Q.P. Code : 262933

Time : Three hours **Answer ALL Questions** **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Discuss the objectives and policies of cGMP. Write the GMP requirements, equipments, and their maintenance for solid dosage form products.

2. Discuss in detail the Physics of Tablet compression. Write a note on effect of particle size and moisture content on the tablet compression.

II. Write notes on: **(7 x 5 = 35)**

1. Sales forecasting Technique.
2. Write a note on Excipient interaction.
3. Explain clearly optimization parameters.
4. Pharmacokinetic parameters.
5. How inventory management influence the production control.
6. Give the detail note about scope and merits of validation.
7. Write the importance of preformulation studies.

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

[MPHARM 0422] **APRIL 2022** **Sub. Code: 2933**

(OCTOBER 2021 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER-I (PCI New regulations 2016)
PHARMACEUTICS - MPH
PAPER III – MODERN PHARMACEUTICS
Q.P. Code : 262933

Time : Three hours **Answer ALL Questions** **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Write in detail about total quality management.

2. Discuss in detail the types, manufacturing methods and evaluation of Large Volume Parenterals (LVP).

II. Write notes on: **(7 x 5 = 35)**

1. Anova test.
2. Objectives of Current Good Manufacturing practice (CGMP).
3. Theories of pharmaceutical dispersions.
4. Types of optimization parameters.
5. Give a note about response surface methodology.
6. Stability testing protocols for tablet dosage form.
7. Types of validation Techniques.

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

[M.PHARM 0922] **SEPTEMBER 2022** **Sub. Code: 2933**
(APRIL 2022 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New regulations 2016)
PHARMACEUTICS - MPH
PAPER III – MODERN PHARMACEUTICS

Q.P. Code : 262933

Time : Three hours **Answer ALL Questions** **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Give an account of the concept and parameters of optimization and write its role in designing the pharmaceutical formulation with applications.

2. Discuss the types, scope and merits of validation. Write the ICH and WHO guidelines for calibration and validation of equipments used for the manufacturing of solid dosage forms.

II. Write notes on: **(7 x 5 = 35)**

1. Physics of Tablet compression.
2. Significance of Chi square test and students t test.
3. Drugs-excipient interactions
4. Factorial designs and its applications.
5. Sales forecasting and budget control in Pharma Industry.
6. ICH guidelines for Stability testing.
7. Pharmacokinetic Parameters.

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

[M.PHARM 0423] APRIL 2023 Sub. Code: 2933
(OCTOBER 2022 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New regulations 2016)
PHARMACEUTICS - MPH
PAPER III – MODERN PHARMACEUTICS

Q.P. Code: 262933

Time: Three hours **Answer ALL Questions** **Maximum: 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Discuss the concept and parameters of optimization and write its role in designing the pharmaceutical formulation with applications.

2. Write a note on the objectives and policies of CGMP. Write the GMP requirements and layout of buildings, services, equipments, and their maintenance for solid dosage form products.

II. Write notes on: **(7 x 5 = 35)**

1. Types of validation.
2. Evaluation of small volume parentrals.
3. Theories of dispersion.
4. Significance of similarity factors.
5. Distribution of forces during compression of tablets.
6. Budget and cost control.
7. Protocols of stability studies.

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

[M.PHARM 0823] AUGUST 2023 Sub. Code: 2933
(APRIL 2023 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACEUTICS - MPH
PAPER III – MODERN PHARMACEUTICS

Q.P. Code: 262933

Time : Three hours **Answer ALL Questions** **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Explain elaborately about Physics of Tablet Compression.

2. Define Pharmaceutical validation and write scope and quality. Discuss about general guidelines for the validation and calibration of manufacturing process model.

II. Write notes on: **(7 x 5 = 35)**

1. Stability testing of Small volume parentrals.
2. Factorial designs and application in pharmaceutical formulation.
3. Describe current Good Manufacturing Practice.
4. Similarity factors (f2).
5. Response surface Methodology.
6. Calibration and Validation of equipments as ICH guidelines.
7. Concept of Total Quality Management.

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

[M.PHARM 1223] DECEMBER 2023 Sub. Code: 2933
(OCTOBER 2023 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACEUTICS - MPH
PAPER III – MODERN PHARMACEUTICS

Q.P. Code: 262933

Time: Three hours **Answer ALL Questions** **Maximum: 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Discuss in detail the effect of friction, distribution of forces and compaction profile during tablet compression.

2. Describe in detail in various methods of determining Drug-excipient interactions.

II. Write notes on: **(7 x 5 = 35)**

1. What are the limitations in formulations of SMEDDS?
2. Explain the response surface designs used for optimization of formulations.
3. What are User Requirement Specifications (URS) for equipments?
4. Discuss the Functions of Production Management.
5. Evaluation of Parenteral Formulations.
6. Discuss the parameter affecting rate of Dissolution.
7. Explain Compatibility profile of Tablet.

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

[M.PHARM 0524] MAY 2024 Sub. Code: 2933
(APRIL 2024 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACEUTICS - MPH
PAPER III – MODERN PHARMACEUTICS

Q.P. Code: 262933

Time: Three hours **Answer ALL Questions** **Maximum: 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Explain the objectives, policies of cGMP, layout of buildings, services, equipments and their maintenance.

2. Explain in detail about the user requirement specification, design qualification, installation qualification, operational qualification and performance qualification of facilities.

II. Write notes on: **(7 x 5 = 35)**

1. Discuss about various types of pharmaceutical validation.
2. State the ANOVA test.
3. Explain the various distribution forces involved in the tablet compression process.
4. Discuss the theories of pharmaceutical dispersions.
5. Describe in detail about similarity factors f_2 and f_1.
6. Discuss about the response surface method in optimization technique.
7. Mention the various techniques to improve the solubility of poorly water soluble drugs.

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

[M.PHARM 0425] **APRIL 2025** **Sub. Code: 2933**

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACEUTICS - MPH
PAPER III – MODERN PHARMACEUTICS

Q.P. Code: 262933

Time: Three hours **Answer ALL Questions** **Maximum: 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Discuss the objectives and policies of cGMP. Explain the GMP requirements, lay out of buildings, equipments and other related services for the manufacturing of Semisolid dosage forms.

2. Explain the requirements of layout, formulation factors, evaluation and stability aspects of the preparation of the Large Volume parenteral products.

II. Write notes on: **(7 x 5 = 35)**

1. Factors improving the solubility of drugs.
2. Significance of linearity concept.
3. Factorial design and application on the formulation.
4. Concept of Total quality Management.
5. Theories of dispersion.
6. Distribution of forces and compaction profiles.
7. Validation of solid dosage forms.

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

[M.PHARM 1025] **OCTOBER 2025** **Sub. Code: 2933**

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACEUTICS - MPH
PAPER III – MODERN PHARMACEUTICS

Q.P. Code: 262933

Time: Three hours **Answer ALL Questions** **Maximum: 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Discuss about the parameters and various optimization techniques in pharmaceutical formulation and processing.

2. Discuss the effect of friction, Distribution of forces and compaction profiles involved in tablet compression process.

II. Write notes on: **(7 x 5 = 35)**

1. Write the concept of total quality management.
2. Discuss about the procedures and limitations involved in the accelerated stability testing.
3. State the scope and merits of pharmaceutical validation.
4. Briefly explain the diffusion and dissolution parameters.
5. Explain the various methods of sales forecasting techniques.
6. Outline the evaluation tests of parenteral dosage forms.
7. Describe the Heckel plot in tablet compression process.

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