

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

[LM 957]

MAY 2018

Sub. Code: 2957

**M.PHARM. DEGREE EXAMINATION**  
**(PCI New regulations 2016)**  
**SEMESTER-II**  
**BRANCH-III – PHARMACEUTICAL ANALYSIS – MPA**  
**PAPER III – QUALITY CONTROL AND QUALITY ASSURANCE**

*Q.P. Code : 262957*

**Time : Three hours**

**Maximum : 75 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. a) Give a detailed account on location and building requirements for pharma industry.  
b) Write note on Good ware housing practice.
2. a) Explain in detail about quality control of packaging materials.  
b) Write note on scope and limitations of Good Laboratory practice.

**II. Write notes on:**

**(7 x 5 = 35)**

1. Controls on animal house.
2. Write note on training.
3. Write note on ICH specification for in process quality control.
4. Explain the principles of cell viability assay (MTT Assay).
5. Write note on *In-vitro* assay of drug metabolites.
6. Design and evaluation of Bioequivalence studies.
7. CPCSEA guidelines.

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

[LN 957]

NOVEMBER 2018

Sub. Code: 2957

**M.PHARM. DEGREE EXAMINATION**  
**(PCI New regulations 2016)**  
**SEMESTER-II**  
**BRANCH-III – PHARMACEUTICAL ANALYSIS – MPA**  
**PAPER III – QUALITY CONTROL AND QUALITY ASSURANCE**

*Q.P. Code : 262957*

**Time : Three hours**

**Maximum : 75 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. Write in detail about the concepts and philosophy of Good Manufacturing Practices.
2. What is In Process Quality control? Discuss briefly the various In Process Quality Control tests carried out for Parenterals and Tablets.

**II. Write notes on:**

**(7 x 5 = 35)**

1. Scope of GLP.
2. CPCSEA guidelines.
3. WHO Certifications.
4. Master Formula Record.
5. Manufacturing Operations for Sanitations.
6. Quality Audit Plan.
7. Purchase specifications for Raw materials.

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

[LO 957]

MAY 2019

Sub. Code: 2957

**M.PHARM. DEGREE EXAMINATION**  
**(PCI New regulations 2016)**  
**SEMESTER-II**  
**BRANCH-III – PHARMACEUTICAL ANALYSIS – MPA**  
**PAPER III – QUALITY CONTROL AND QUALITY ASSURANCE**

*Q.P. Code : 262957*

**Time : Three hours**

**Maximum : 75 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. Explain in detail about the overview of ICH GUIDELINES for QSEM and Q-Series guidelines.
2. Write note on c GMP GUIDELINES for the Organisations and Personal Responsibilities.

**II. Write notes on:**

**(7 x 5 = 35)**

1. Concepts of Auditing.
2. What are the tests to be performed for assuring quality of Glass?
3. How the quality control of Liquid Orals is achieved?
4. Analysis of Raw materials.
5. Control on Animal House.
6. Release of Finished Products.
7. Good Warehousing Practice.

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

[LP 957]

NOVEMBER 2019

Sub. Code: 2957

**M.PHARM. DEGREE EXAMINATION**  
**(PCI New regulations 2016)**  
**SEMESTER-II**  
**BRANCH-III – PHARMACEUTICAL ANALYSIS – MPA**  
**PAPER III – QUALITY CONTROL AND QUALITY ASSURANCE**

*Q.P. Code : 262957*

**Time : Three hours**

**Maximum : 75 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. a) Describe in detail about Good Laboratory Practice.  
b) Write note on plant layout and construction of Pharma industry.
2. a) Write note on analysis of raw materials and finished products.  
b) Master formula records.

**II. Write notes on:**

**(7 x 5 = 35)**

1. Write note on Quality Assurance unit.
2. Describe the protocol for conducting non clinical testing.
3. Write note on sanitation in Pharma industry.
4. Write note on in process quality control.
5. Standard operating procedure.
6. Quality audit.
7. Write note on maintenance of sterile area.

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

**[LQ 0121]**

**JANUARY 2021**

**Sub. Code: 2957**

**(APRIL 2020 EXAM SESSION)**

**M.PHARMACY DEGREE EXAMINATION**

**SEMESTER-II (PCI New regulations 2016)**

**PHARMACEUTICAL ANALYSIS – MPA**

**PAPER III – QUALITY CONTROL AND QUALITY ASSURANCE**

***Q.P. Code : 262957***

**Time : Three hours**

**Answer ALL Questions**

**Maximum : 75 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. What do you mean by SOP? Write in detail about SOP of different manufacturing process.
2. a) Write note on release of finished product.  
b) Master formula record.

**II. Write notes on:**

**(7 x 5 = 35)**

1. Control on animal house.
2. ICH guidelines.
3. Good Warehousing Practice.
4. Distribution records.
5. Aseptic process control.
6. Quality control test for closures.
7. Environmental control.

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

**[MPHARM 0921]**

**SEPTEMBER 2021  
(OCTOBER 2020 EXAM SESSION)**

**Sub. Code: 2957**

**M.PHARMACY DEGREE EXAMINATION  
SEMESTER-II (PCI New regulations 2016)  
PHARMACEUTICAL ANALYSIS - MPA  
PAPER III – QUALITY CONTROL AND QUALITY ASSURANCE  
*Q.P. Code : 262957***

**Time : Three hours**

**Answer ALL Questions**

**Maximum : 75 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. a) Write note on GMP.  
b) Explain the overview of ICH guidelines with special emphasis on Q-Series.
2. a) Write note on C GMP guidelines for the organisations and personal responsibilities.  
b) Good warehousing practices.

**II. Write notes on:**

**(7 x 5 = 35)**

1. Quality assurance unit.
2. CPCSEA guidelines.
3. Purchase specifications of raw materials.
4. Batch formula record.
5. Sanitation of manufacturing premises.
6. Release of finished products.
7. Quality control test for containers.

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

**[MPHARM 0122]**

**JANUARY 2022  
(APRIL 2021 EXAM SESSION)**

**Sub. Code: 2957**

**M.PHARMACY DEGREE EXAMINATION  
SEMESTER-II (PCI New regulations 2016)  
PHARMACEUTICAL ANALYSIS - MPA  
PAPER III – QUALITY CONTROL AND QUALITY ASSURANCE  
*Q.P. Code : 262957***

**Time : Three hours**

**Answer ALL Questions**

**Maximum : 75 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. a) Explain in detail about ICH guidelines for QSEM.  
b) Write note on Quality assurance unit and control on Animal house.
2. Explain in detail about in process quality control and finished product quality control of tablets and capsules.

**II. Write notes on:**

**(7 x 5 = 35)**

1. Concept of auditing.
2. Plant layout.
3. Good warehousing practice.
4. Maintenance of Raw materials store.
5. Master formula record.
6. Standard operation procedure concept.
7. Aseptic process control.

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

**[M.PHARM 0922]**

**SEPTEMBER 2022  
(APRIL 2022 EXAM SESSION)**

**Sub. Code: 2957**

**M.PHARMACY DEGREE EXAMINATION  
SEMESTER - II (PCI New regulations 2016)  
PHARMACEUTICAL ANALYSIS - MPA  
PAPER III – QUALITY CONTROL AND QUALITY ASSURANCE**

*Q.P. Code : 262957*

**Time : Three hours**

**Answer ALL Questions**

**Maximum : 75 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. Discuss in detailed on quality, safety, efficacy and multidisciplinary guidelines.
2. Explain the master formula record and batch formula record.

**II. Write notes on:**

**(7 X 5 =35)**

1. In-process quality control test for tablets.
2. Sanitation of manufacturing premises.
3. Quality control for secondary packing materials.
4. Premises, location and building requirements for pharma industry.
5. Restrictions on animal house.
6. Need for distribution records in pharma industry.
7. CPCSEA guidelines.

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

**[M.PHARM 0823]**

**AUGUST 2023  
(APRIL 2023 EXAM SESSION)**

**Sub. Code: 2957**

**M.PHARMACY DEGREE EXAMINATION  
SEMESTER - II (PCI New Regulations 2016)  
PHARMACEUTICAL ANALYSIS - MPA  
PAPER III – QUALITY CONTROL AND QUALITY ASSURANCE**

*Q.P. Code: 262957*

**Time : Three hours**

**Answer ALL Questions**

**Maximum : 75 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. Explain the quality control test for containers, closures and secondary packing.
2. Discuss on prevention of mix-up and cross contamination.

**II. Write notes on:**

**(7 X 5 =35)**

1. Protocol for control on animal house.
2. Organization and personnel responsibilities.
3. Retention and retrieval.
4. Maintenance of stores for raw materials.
5. Expiry date calculation.
6. Master formula record.
7. Good manufacturing practice.

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

**[M.PHARM 1223]**

**DECEMBER 2023  
(OCTOBER 2023 EXAM SESSION)**

**Sub. Code: 2957**

**M.PHARMACY DEGREE EXAMINATION  
SEMESTER - II (PCI New Regulations 2016)  
PHARMACEUTICAL ANALYSIS - MPA  
PAPER III – QUALITY CONTROL AND QUALITY ASSURANCE**

*Q.P. Code: 262957*

**Time: Three hours**

**Answer ALL Questions**

**Maximum: 75 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. Explain the in-process quality control for parenterals and capsules.
2. Describe the standard operating procedures for documentation in pharmaceutical industry.

**II. Write notes on:**

**(7 X 5 =35)**

1. Packaging materials.
2. Good warehousing practice.
3. Protocol for conduct non clinical testing.
4. Good laboratory practice.
5. Pharmaceutical inspection convention.
6. Environmental control act.
7. Aseptic process control.

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

**[M.PHARM 0524]**

**MAY 2024  
(APRIL 2024 EXAM SESSION)**

**Sub. Code: 2957**

**M.PHARMACY DEGREE EXAMINATION  
SEMESTER - II (PCI New Regulations 2016)  
PHARMACEUTICAL ANALYSIS - MPA  
PAPER III – QUALITY CONTROL AND QUALITY ASSURANCE**

*Q.P. Code: 262957*

**Time: Three hours**

**Answer ALL Questions**

**Maximum: 75 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. Write a note in process Quality control test carried out for capsules, ointments and creams.
2. a) Brief note on Quality assurance unit and write note on non-clinical testing.  
b) CPCSEA guidelines.

**II. Write notes on:**

**(7 X 5 =35)**

1. GLP.
2. Write note on Hygiene.
3. Raw material purchase specifications.
4. Batch formula record.
5. Release of finished product.
6. Describe about Evaluation of Sterile products.
7. Sanitation of manufacturing process.

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

**[M.PHARM 0425]**

**APRIL 2025**

**Sub. Code: 2957**

**M.PHARMACY DEGREE EXAMINATION  
SEMESTER - II (PCI New Regulations 2016)  
PHARMACEUTICAL ANALYSIS - MPA  
PAPER III – QUALITY CONTROL AND QUALITY ASSURANCE**

*Q.P. Code: 262957*

**Time: Three hours**

**Answer ALL Questions**

**Maximum: 75 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. Write in detail about Purchase Specifications and maintenance of stores for raw materials.
2. Write in detail about Quality control on Packaging Materials.

**II. Write notes on:**

**(7 X 5 =35)**

1. Maintenance of Sanitation in manufacturing premises.
2. Write shortly on Quality audit plan.
3. Handling of waste and scrap disposal.
4. Describe about Aseptic process control.
5. Write note on Good warehousing practice.
6. Write note on process deviations and charge- in of components.
7. Discuss about the concepts of trademark, copyright and patents.

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

**[M.PHARM 1025]**

**OCTOBER 2025**

**Sub. Code: 2957**

**M.PHARMACY DEGREE EXAMINATION  
SEMESTER - II (PCI New Regulations 2016)  
PHARMACEUTICAL ANALYSIS - MPA  
PAPER III – QUALITY CONTROL AND QUALITY ASSURANCE**

*Q.P. Code: 262957*

**Time: Three hours**

**Answer ALL Questions**

**Maximum: 75 Marks**

**I. Elaborate on:**

**(2 x 20 = 40)**

1. What do you mean by SOP? Write in detail about SOP of different manufacturing process.
2. a) Write note on release of finished product.  
b) Master formula record.

**II. Write notes on:**

**(7 X 5 =35)**

1. Control on animal house.
2. ICH guidelines.
3. Good Warehousing Practice.
4. Distribution records.
5. Aseptic process control.
6. Quality control test for closures.
7. Environmental control.

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