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

**[LL 953]** NOVEMBER 2017 **Sub. Code: 2953**

**M.PHARM. DEGREE EXAMINATION**
**(PCI New regulations 2016)**
**SEMESTER-I**
**PHARMACEUTICAL ANALYSIS – MPA**
**PAPER III – PHARMACEUTICAL VALIDATION**

***Q.P. Code : 262953***

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

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

1. Write the general principles involved in analytical method validation as per ICH guidelines.

2. Give the definition, advantage and streamlining of qualification and validation process.

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

1. Factory Acceptance Test (FAT).
2. Qualification of Electronic balance.
3. Validation of HVAC System.
4. Electronic records.
5. Types of patent applications.
6. Performance qualification.
7. Rights and responsibilities of patentee.

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

**[LM 953]** MAY 2018 **Sub. Code: 2953**

**M.PHARM. DEGREE EXAMINATION**
**(PCI New regulations 2016)**
**SEMESTER-I**
**PHARMACEUTICAL ANALYSIS – MPA**
**PAPER III – PHARMACEUTICAL VALIDATION**

***Q.P. Code : 262953***

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

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

1. Explain the qualification of FTIR, GC.

2. Discuss the role of intellectual property in Pharmaceutical Industry, Global ramification and financial implications.

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

1. Site Acceptance Test (SAT).
2. Qualification of Pipette and measuring cylinder.
3. Validation of pharmaceutical water system and pure steam.
4. GAMP-5.
5. International patenting requirement procedure.
6. Operational qualification.
7. Penalties for Violation in Intellectual property.

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

**[LN 953]** NOVEMBER 2018 **Sub. Code: 2953**

**M.PHARM. DEGREE EXAMINATION**
**(PCI New regulations 2016)**
**SEMESTER-I**
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**PAPER III – PHARMACEUTICAL VALIDATION**

***Q.P. Code : 262953***

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

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

1. Discuss the validation master plan, advantages of validation and performance qualification.

2. Write the general principles of analytical method validation and also write ICH guidelines for method validation of High Performance Liquid Chromatography (HPLC).

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

1. Significance of transfer technology.
2. Factory acceptance test.
3. Qualification of measuring cylinder.
4. Validation of analytical method used in cleaning.
5. Digital significance in computerized system validation.
6. Intellectual Property Rights (IPR).
7. Global ramifications and financial implications.

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

**[LO 953]** MAY 2019 **Sub. Code: 2953**

**M.PHARM. DEGREE EXAMINATION**
**(PCI New regulations 2016)**
**SEMESTER-I**
**BRANCH III – PHARMACEUTICAL ANALYSIS – MPA**
**PAPER III – PHARMACEUTICAL VALIDATION**

***Q.P. Code : 262953***

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

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

1. Explain the qualification of UV-Visible Spectrophotometer, and HPLC.

2. Write the concepts of Intellectual Property (IP), Intellectual Property Protection (IPP) and Intellectual Property Rights (IPR).

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

1. Validation Master Plan.
2. Qualification of beaker and burette.
3. Cleaning validation of equipment.
4. 21CFR part II.
5. Significance of transfer Technology (TOT).
6. Installation qualification.
7. Factors affecting choice of IP protection.

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

**[LP 953]** NOVEMBER 2019 **Sub. Code: 2953**

**M.PHARM. DEGREE EXAMINATION**
**(PCI New regulations 2016)**
**SEMESTER-I**
**BRANCH III – PHARMACEUTICAL ANALYSIS – MPA**
**PAPER III – PHARMACEUTICAL VALIDATION**

***Q.P. Code : 262953***

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

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

1. Define Qualification and briefly explain about Validation process & Master plan.

2. a) Describe in detail about the Global ramification and financial implication.
   b) Explain about Intellectual Property Protection (IPP).

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

1. Write a note on Operational Qualification.
2. Discuss about the Calibration of UV-Visible Spectrophotometer.
3. Describe about the Significance of Transfer Technology.
4. Explain about the Practical aspects regarding maintaining of Patent file.
5. Discuss about Cleaning Validation.
6. Briefly explain about computerized system validation.
7. Give a detail note on Concepts of Intellectual Property

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

**[LQ 0121] JANUARY 2021 Sub. Code: 2953**

**(APRIL 2020 EXAM SESSION)**

**M.PHARMACY DEGREE EXAMINATION**

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

**PHARMACEUTICAL ANALYSIS – MPA**

**PAPER III – PHARMACEUTICAL VALIDATION**

***Q.P. Code : 262953***

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

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

1. Discuss in detail about the Validation of utility system in Pharmaceutical water system & pure steam.

2. Explain in detail about the Qualification of Analytical Instruments (UV-Visible, FTIR, GC and HPLC).

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

1. Write a note on Site Acceptance test.
2. Discuss about the Calibration of HPLC.
3. Write a note on Compressed air & nitrogen.
4. Explain about the Qualification of Manufacturing equipment
5. What was the Role of Intellectual property (IP) in Pharmaceutical industry?
6. Briefly explain about Trademark and Copyright.
7. Write the steps to be followed in Cleaning of Equipment.

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

**[MPHARM 0921] SEPTEMBER 2021 Sub. Code: 2953**
**(OCTOBER 2020 EXAM SESSION)**

**M.PHARMACY DEGREE EXAMINATION**
**SEMESTER-I (PCI New regulations 2016)**
**PHARMACEUTICAL ANALYSIS - MPA**
**PAPER III – PHARMACEUTICAL VALIDATION**
***Q.P. Code : 262953***

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

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

1. Give the definition of validation, advantages, streamlining of qualification and validation master plan.

2. Write the qualification of analytical instruments of the following:
   a) GC.
   b) UV – Visible spectrophotometer.
   c) FTIR.

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

1. Give the advantages of validation.
2. HVAC system.
3. Performance Qualification.
4. Explain the types of patent application.
5. What is the Rights and responsibilities of Patentee.
6. Qualification of Burette and Pipette.
7. Cleaning validation of any one equipment.

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

**[MPHARM 0122] JANUARY 2022 Sub. Code: 2953**
**(APRIL 2021 EXAM SESSION)**

**M.PHARMACY DEGREE EXAMINATION**
**SEMESTER-I (PCI New regulations 2016)**
**PHARMACEUTICAL ANALYSIS - MPA**
**PAPER III – PHARMACEUTICAL VALIDATION**
***Q.P. Code : 262953***

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

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

1. Define Qualification. Explain about the installation qualification and Operational qualification.

2. a) Write the Calibration procedure for burette and HPLC.
   b) Write in detail about the validation master plan and its importance.

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

1. Write a note on Re-qualification.
2. Site acceptance test [SAT].
3. Write an account on streamlining of Qualification.
4. Explain the need of Intellectual property Right and their Economic Importance.
5. Qualification of Electronic balance.
6. Qualification of pH meter.
7. Performance Qualification.

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

**[MPHARM 0422] APRIL 2022 Sub. Code: 2953**
**(OCTOBER 2021 EXAM SESSION)**

**M.PHARMACY DEGREE EXAMINATION**
**SEMESTER-I (PCI New regulations 2016)**
**PHARMACEUTICAL ANALYSIS - MPA**
**PAPER III – PHARMACEUTICAL VALIDATION**
***Q.P. Code : 262953***

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

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

1. Explain in detail about the validation of analytical methods as per ICH guidelines with suitable examples.

2. a) Briefly explain about computerized system validation.
   b) Significance of transfer technology.
   c) Penalties for Violation in Intellectual property.

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

1. Write a note on calibration and preventive maintenance.
2. Write briefly about GAMP – 5.
3. Write a note on Electronic records and Digital signature – 21.
4. Write a note on calibration and preventive maintenance.
5. Explain the validation of compressed air and nitrogen.
6. Write note on design qualification.
7. Write a note on cleaning in place (CIP).

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