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

[M.PHARM 0423] APRIL 2023 Sub. Code: 3001
(OCTOBER 2022 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER I – GOOD REGULATORY PRACTICES

Q.P. Code: 263001

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

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

1. GDP (good distribution practices) is a quality warranty system for purchasing, receiving, storing and exporting drugs.

2. How can one ensure data quality and integrity by maintaining good laboratory practices (GLP)?

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

1. Principles of GALP.
2. Global Harmonization Task Force (GHTF).
3. Validation master file.
4. Software evaluation checklist.
5. Six sigma concept.
6. WHO cGMP guidelines.
7. Quality by design (QbD).

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

[M.PHARM 0823] **AUGUST 2023** **Sub. Code: 3001**
(APRIL 2023 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER I – GOOD REGULATORY PRACTICES

Q.P. Code: 263001

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

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

1. US current Good Manufacturing Practices (cGMP) Part 210 and Part 211.

2. Good Automated Laboratory Practices (GALP). Give the principles and requirements of GALP.

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

1. Global Harmonization Task Force (GHTF).
2. Audit and inspection process of GLP.
3. Quality Control of India (QCI) standards.
4. Software evaluation checklist.
5. GDP requirements for premises and equipment.
6. Supply chain integrity.
7. Quality by Design (QbD).

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

[M.PHARM 0524] MAY 2024 Sub. Code: 3001
(APRIL 2024 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER I – GOOD REGULATORY PRACTICES

Q.P. Code: 263001

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

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

1. Quality, safety, efficacy, multidisciplinary (QSEM) and Quality guidelines as per the International Council for Harmonisation.

2. General principles and legal regulations of the distribution of pharmaceutical products on Good Documentation Practices as per World Health Organization.

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

1. In vitro diagnostic Medical Devices Global Harmonization Task Force.
2. Current Good Manufacturing Practice guidelines according to World Health Organization.
3. Quality Audit as per Indian Standard Organization. Add a note on audit tools and their responsibilities.
4. Good Automated Laboratory Practices principles and requirements in brief.
5. Principles and documentation of Good Documentation Practices.
6. Relevant Central Drug Standard Control Organization guidelines involved in Good Documentation Practices.
7. Concepts of six sigma and its methods of Define, Measure, Analyse, Improve and Control (DMAIC) and Define Measure, Analyse, Design and verify (DMADV).

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

[M.PHARM 0425] **APRIL 2025** **Sub. Code: 3001**

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER I – GOOD REGULATORY PRACTICES

Q.P. Code: 263001

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

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

1. Checklist as per World Health Organization cGMP standards and how to write a general checklist for the validation of electronic records and a digital signature?

2. Why was Good Laboratory Practice created? Explain the regulations of 21 Code of Federal Regulations Part 58 and its fundamental points.

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

1. Why current Good Manufacturing Practice is important? Describe the regulations of 21 Code of Federal Regulations Part 11.
2. Explain control of components and drug product containers and closures of cGMP.
3. How to control the Good Laboratory Practice inspection process?
4. Explain the procedure to write SOP and explain about SOPs of Good Automated Laboratory Practice.
5. Write relevant international standard organization and Quality Council of India standards of Good Laboratory Practice.
6. Good Documentation Practice guidelines according to United States Pharmacopoeia.
7. Clarify the steps involved in the qualification of Heating Ventilation and Air Conditioning System (HVAC).

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