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

[M.PHARM 0423] APRIL 2023 Sub. Code: 3002
(OCTOBER 2022 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER II – DOCUMENTATION AND REGULATORY WRITING

Q.P. Code: 263002

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

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

1. Outline the importance of Electronic Submission Gateway with appropriate examples.

2. Explain about the preparation and conduct of audit guidelines in pharma industry with suitable examples. Add a note on quality and GMP audit.

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

1. Write in brief about vendor qualification.
2. Discuss the significance of annual product reviews, batch review and batch release.
3. Write importance of documentation. Explain master production and control records.
4. Differentiate between drug master file (DMF) and site master file (SMF).
5. Illustrate with examples the outcome of inspection of pharmaceutical manufacturers.
6. Give the overview and essentials of GHTF study group 4 guidance documents.
7. Write the salient features of CBE ‘0’ and ‘30’ days.

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

[M.PHARM 0823] **AUGUST 2023** **Sub. Code: 3002**
(APRIL 2023 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER II – DOCUMENTATION AND REGULATORY WRITING

Q.P. Code: 263002

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

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

1. The different types of audits and write brief notes on process of preparation and conducting an audit.

2. The contents and organisation of a dossier. Explain its compilation and review.

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

1. Master Formula Record (MFR).
2. Inspection of drug distribution channels.
3. Inspection report.
4. Product development plan.
5. Scale Up and Post Approval Changes (SUPAC).
6. Root cause analysis and CAPA.
7. Quality system requirements for national GMP inspectorate.

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

[M.PHARM 0524] MAY 2024 Sub. Code: 3002
(APRIL 2024 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER II – DOCUMENTATION AND REGULATORY WRITING

Q.P. Code: 263002

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

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

1. Discuss in detail about exploratory product development brief (EPDB) for drug substance and drug product.

2. Explain the submission of dossier in Sugam system of CDSCO. Add a note on ACTD.

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

1. Explain the needs of warning letter in Pharma industry with suitable examples.
2. Write down the benefits of external audit.
3. Give a note on handling of recall and complaint records.
4. Write the salient features of Pre-approval inspections.
5. Differentiate between generic and brand products.
6. Write the salient features of Scale up management of drug products.
7. Explain revised Scheduled M.

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

[M.PHARM 0425] **APRIL 2025** **Sub. Code: 3002**

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER II – DOCUMENTATION AND REGULATORY WRITING

Q.P. Code: 263002

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

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

1. Batch manufacturing record and its calculations. Add a note on batch reconciliation.

2. Contents and organisation of a dossier. Explain its compilation and review.

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

1. Planning and requirements of electronic dossier submission.
2. Different modules of a Common Technical Document (CTD).
3. Contents of site master file.
4. Inspection of drug distribution channels.
5. Establishment inspectional report.
6. Warning letters, recalls, seizures and injunctions.
7. Electronic submission gateway.

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