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Title:	Document and Data Control	**Version:**	1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
Location:	Pune, India	**Review Date:**	2026-01-01

Document and Data Control

Category: Quality Assurance

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Quality Assurance

Title: Document and Data Control

SOP No.: SOP-QA-003

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1.0 PURPOSE

This procedure establishes and maintains a system for controlling documents and data, both paper-based and electronic, generated, received, and retained in pharmaceutical manufacturing at NovaThera Pharmaceuticals Pvt. Ltd., ensuring compliance with Good Manufacturing Practices (GMP) and regulatory requirements. This procedure aims to prevent the use of unauthorized, obsolete, or invalid documents and data, ensuring data integrity, traceability, and availability.

2.0 SCOPE

This SOP applies to all departments and personnel at NovaThera Pharmaceuticals Pvt. Ltd. involved in the creation, review, approval, distribution, revision, storage, and retrieval of documents and data related to pharmaceutical manufacturing activities, including but not limited to: specifications, standard test procedures, manufacturing batch records, analytical data, validation protocols and reports, equipment operating procedures, training records, audit reports, and quality control records. This procedure covers both paper and electronic records. It applies to all products manufactured by NovaThera Pharmaceuticals Pvt. Ltd., regardless of batch size or dosage form.

3.0 RESPONSIBILITY

QC Inspector:

- Verifies document completeness and accuracy prior to archiving.
- Conducts periodic reviews of archived documents to ensure legibility and integrity.
- Reports any discrepancies or issues to the QA Manager.

Production Supervisor:

- Ensures that all production personnel are trained on the document and data control SOP.
- Ensures that only approved and current versions of documents are used in production activities.
- Immediately removes obsolete documents from the production area.
- Reports any document discrepancies to the QA Manager.

QA Manager:

- Develops, maintains, and reviews this SOP and associated procedures.
- Ensures that all documents are properly reviewed, approved, and distributed.
- Manages the document control system, including electronic document management systems (EDMS), if applicable.
- Conducts training on document control procedures.
- Investigates and resolves document control deviations.
- Oversees the archiving and retrieval of documents.
- Performs periodic audits of the document control system.

Head of QA:

- Approves this SOP and any revisions.
- Provides overall oversight of the document control system.
- Ensures that the document control system meets all regulatory requirements.
- Ensures resources are available for effective document control.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses
- Gloves

Equipment:

- Computer with access to network and relevant software applications (e.g., EDMS)
- Printer
- Scanner
- Photocopier

- Calibrated temperature and humidity monitoring device (if applicable, for archive storage)
- Archive boxes (acid-free, archival quality)
- Binder Clips
- Shredder

Documentation:

- Document Change Request Form (QA-F-001)
- Document Review Form (QA-F-002)
- Master Document List (QA-R-001)
- Document Distribution Log (QA-R-002)
- Archive Inventory Log (QA-R-003)
- Electronic Document Management System (EDMS) User Manual (if applicable)

5.0 PROCEDURE

5.1 Document Creation and Revision

5.1.1 The department requiring a new document or revision of an existing document shall initiate a Document Change Request Form (QA-F-001). The form should clearly state the purpose of the document/revision, the rationale for the change, and the impact on other documents or processes.

5.1.2 The originator prepares the draft document or revision, ensuring that the content is accurate, clear, concise, and compliant with relevant GMP guidelines and company policies. The document should follow the company's established template and formatting guidelines.

5.1.3 The draft document or revision is submitted to the appropriate subject matter expert (SME) for review. The SME reviews the document for technical accuracy, completeness, and compliance.

5.1.4 The reviewer documents their review using the Document Review Form (QA-F-002), indicating any necessary corrections or modifications.

5.1.5 The originator addresses the reviewer's comments and revises the document accordingly.

5.1.6 The revised document, along with the completed Document Change Request Form (QA-F-001) and Document Review Form (QA-F-002), is submitted to the QA Manager for approval.

5.2 Document Approval

5.2.1 The QA Manager reviews the document for overall quality, completeness, and compliance with GMP and company policies. The review includes verifying that all required sections are present, that the content is accurate and consistent, and that the document is properly formatted.

5.2.2 If the QA Manager identifies any issues, the document is returned to the originator for correction.

5.2.3 Once the QA Manager is satisfied with the document, it is forwarded to the Head of QA for final approval.

5.2.4 The Head of QA reviews the document to ensure it meets the required standards and approves the document by signing and dating the approval section.

5.2.5 Upon approval, the QA Manager assigns a unique document number and version number to the document. The document number should follow the established company naming convention. The version number starts at 1.0 for new documents and is incremented for each revision.

5.2.6 The effective date of the document is recorded as 2025-01-01.

5.3 Document Distribution and Retrieval

5.3.1 The QA Manager updates the Master Document List (QA-R-001) to reflect the new or revised document. The Master Document List includes the document number, title, version number, effective date, and location of the document (electronic or physical).

5.3.2 The QA Manager distributes the approved document to the relevant departments and personnel, as identified in the Document Change Request Form (QA-F-001). Distribution can be electronic (e.g., via email or EDMS) or physical (e.g., paper copies).

5.3.3 The QA Manager records the distribution of the document in the Document Distribution Log (QA-R-002), including the recipient's name, department, date of distribution, and method of distribution.

5.3.4 When a document is revised, the QA Manager retrieves all obsolete copies of the document from the users.

5.3.5 Obsolete documents are clearly marked as "OBSOLETE" and removed from active use. Paper copies are either destroyed using a shredder or retained in an archive. Electronic copies are moved to an archive folder or designated as inactive in the EDMS.

5.3.6 Only the current approved version of a document shall be available for use in manufacturing, testing, or other GMP-related activities.

5.4 Electronic Document Management System (EDMS) (If Applicable)

5.4.1 If NovaThera Pharmaceuticals Pvt. Ltd. utilizes an EDMS, all document control procedures shall be implemented within the system.

5.4.2 Access to the EDMS shall be controlled through user accounts and permissions, ensuring that only authorized personnel can create, review, approve, and access documents.

5.4.3 The EDMS shall provide version control, audit trails, and electronic signatures to ensure data integrity and traceability.

5.4.4 The EDMS shall be validated to ensure that it meets all regulatory requirements and performs as intended.

5.4.5 User training shall be provided on the proper use of the EDMS. Refer to the Electronic Document Management System (EDMS) User Manual for detailed instructions.

5.5 Document Storage and Archiving

5.5.1 All documents, both paper-based and electronic, shall be stored in a secure location that protects them from damage, deterioration, and unauthorized access.

5.5.2 Paper-based documents shall be stored in archive boxes (acid-free, archival quality) and organized according to document type and date.

5.5.3 The archive location shall be maintained at a controlled temperature and humidity to prevent degradation of the documents. The temperature and humidity should be monitored and recorded regularly.

5.5.4 Electronic documents shall be backed up regularly to prevent data loss. Backups should be stored in a separate location from the original documents.

5.5.5 An Archive Inventory Log (QA-R-003) shall be maintained to track the location and contents of all archived documents.

5.5.6 Documents shall be retained for the period specified in the company's record retention policy, which should comply with all applicable regulatory

requirements.

5.5.7 Access to the archive shall be restricted to authorized personnel only.

5.6 Data Control

5.6.1 All data, whether generated electronically or manually, shall be accurate, complete, consistent, and reliable.

5.6.2 Data shall be recorded contemporaneously with the activity being performed.

5.6.3 Data shall be attributable to the person who generated it.

5.6.4 Data shall be legible and permanent.

5.6.5 Electronic data shall be protected from unauthorized access, alteration, or deletion.

5.6.6 Audit trails shall be enabled for electronic data to track all changes made to the data, including the user, date, time, and reason for the change.

5.6.7 Data shall be reviewed and approved by a qualified individual before being used for decision-making.

5.6.8 Data shall be retained for the period specified in the company's record retention policy.

6.0 POST-DOCUMENT CONTROL ACTIVITIES

6.1 The QA Manager shall conduct periodic audits of the document and data control system to ensure that it is functioning effectively and that all procedures are being followed.

6.2 The audit findings shall be documented and reported to the Head of QA.

6.3 Corrective and preventive actions (CAPA) shall be implemented to address any deficiencies identified during the audits.

6.4 The effectiveness of the CAPA shall be monitored to ensure that the problems have been resolved and do not recur.

6.5 The Master Document List (QA-R-001) shall be reviewed at least annually to ensure that it is accurate and up-to-date.

6.6 This SOP shall be reviewed and updated at least every two years, or more frequently if necessary, to reflect changes in regulations, company policies, or best practices.

7.0 SAFETY PRECAUTIONS

7.1 When handling paper documents, avoid sharp edges to prevent cuts.

7.2 When using electronic equipment (computers, printers, scanners), follow all safety guidelines provided by the manufacturer.

7.3 Ensure that the archive location is well-lit and free from hazards.

7.4 Use proper lifting techniques when moving archive boxes to prevent back injuries.

7.5 When shredding documents, use appropriate safety precautions to avoid injury.

7.6 Wear appropriate PPE (safety glasses, gloves) when handling chemicals or other hazardous materials in the archive location.

8.0 APPROVALS

Prepared By: QA Officer

Reviewed By: QA Manager

Approved By: Head of QA

Date: [Leave blank for manual completion]

Controlled Document Notice

Document Approval

Role	Name	Signature	Date
Prepared by:	_____	_____	_____
Reviewed by (QA):	_____	_____	_____
Approved by (Head QA):	_____	_____	_____

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