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Title:	SOP for SOPs (The procedure for writing, reviewing, approving, and distributing all other SOPs)	**Version:**	1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
Location:	Pune, India	**Review Date:**	2026-01-01

SOP for SOPs (The procedure for writing, reviewing, approving, and distributing all other SOPs)

Category: Quality Assurance

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd., Pune, India

Department: Quality Assurance

Title: SOP for SOPs (The procedure for writing, reviewing, approving, and distributing all other SOPs)

SOP No.: SOP-QA-001

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1.0 PURPOSE

This procedure establishes a standardized system for the creation, review, approval, revision, and distribution of Standard Operating Procedures (SOPs) at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India. This SOP ensures that all SOPs are consistently formatted, accurate, and compliant with current Good Manufacturing Practices (cGMP) and relevant regulatory guidelines for pharmaceutical manufacturing. This SOP ensures that only the current, approved version of an SOP is in use, and that obsolete versions are properly archived and removed from circulation.

2.0 SCOPE

This SOP applies to all departments and personnel within NovaThera Pharmaceuticals Pvt. Ltd. involved in the creation, revision, review, approval, distribution, and archival of SOPs. This includes, but is not limited to, Quality Assurance, Production, Quality Control, Engineering, and Materials Management. This SOP governs all SOPs related to pharmaceutical manufacturing, testing, packaging, storage, and distribution activities at NovaThera Pharmaceuticals Pvt. Ltd. All SOPs generated within NovaThera Pharmaceuticals Pvt. Ltd. must adhere to the guidelines outlined in this document.

3.0 RESPONSIBILITY

QC Inspector: Responsible for reviewing SOPs to ensure the clarity, accuracy, and completeness of quality control related procedures. They will provide feedback to the originating department during the review process and participate in periodic reviews of existing SOPs.

Production Supervisor: Responsible for reviewing SOPs related to production processes to ensure accuracy, clarity, and practicality within the production environment. They will also ensure that all production personnel are trained on the current, approved versions of relevant SOPs.

QA Manager: Responsible for overseeing the SOP management system, ensuring compliance with regulatory requirements and internal procedures. They will facilitate the review and approval process, maintain the SOP database, and coordinate periodic reviews of SOPs. They also manage the training program for all personnel on SOPs.

Head of QA: Responsible for the final approval of all SOPs and revisions, ensuring that they meet all regulatory and internal requirements. They are also responsible for resolving any conflicts or discrepancies that may arise during the review and approval process. The Head of QA ensures that the SOP system is adequately maintained and compliant.

4.0 MATERIALS & EQUIPMENT

PPE: Safety glasses, laboratory coats, appropriate gloves (nitrile, latex, or equivalent) as required by the procedures described in the SOPs being written.

Equipment: Computer with access to the network, printer, scanner, software for document creation and management (e.g., Microsoft Word, Adobe Acrobat), SOP template (electronic version).

Documentation: SOP template (electronic and hard copy), SOP tracking log (electronic or paper-based), Change Control Request Form, Training Record Form, Deviation Report Form.

5.0 PROCEDURE

5.1 SOP Creation

5.1.1 The originating department identifies the need for a new SOP or a revision to an existing SOP. This need may arise from a change in process, equipment, regulatory requirements, or identified gaps in current procedures. A Change Control Request Form must be initiated and approved prior to the creation or revision of any SOP.

5.1.2 The originating department designates a qualified individual to draft the SOP. This individual should have a thorough understanding of the process or activity being described in the SOP.

5.1.3 The designated individual obtains the current SOP template (SOP-QA-001, Version 1.0) from the QA Manager or the designated electronic location on the company network.

5.1.4 The designated individual completes all sections of the SOP template, ensuring that the language is clear, concise, and unambiguous. The SOP must include all necessary steps to perform the activity, including safety precautions, quality control checkpoints, and documentation requirements.

5.1.5 The designated individual includes specific equipment codes, such as BLN-04 for blenders, TCP-01 for tablet press, and SFT-02 for sifter where applicable.

5.1.6 The designated individual ensures that the SOP adheres to all applicable GMP and regulatory requirements.

5.1.7 The designated individual saves the SOP with a unique SOP number, following the established naming convention (e.g., SOP-Department-XXX, where XXX is a sequential number).

5.1.8 The designated individual submits the draft SOP, along with the approved Change Control Request Form, to the originating department's supervisor or manager for review.

5.2 Internal Review

5.2.1 The department supervisor or manager reviews the draft SOP for accuracy, completeness, and clarity. They ensure that the SOP aligns with current practices and regulatory requirements.

5.2.2 The department supervisor or manager may request revisions to the SOP as necessary.

5.2.3 Once the department supervisor or manager is satisfied with the draft SOP, they forward it to the QA Manager for review.

5.2.4 The QA Manager reviews the SOP to ensure compliance with GMP regulations, internal policies, and the overall SOP management system.

5.2.5 The QA Manager verifies that the SOP is consistent with other related SOPs and that it does not conflict with any existing procedures.

5.2.6 The QA Manager reviews the SOP to ensure it follows the format outlined in SOP-QA-001.

5.2.7 The QA Manager ensures that the SOP contains appropriate quality control checkpoints and that documentation requirements are clearly defined.

5.2.8 The QA Manager may request revisions to the SOP as necessary and will collaborate with the originating department to address any concerns.

5.2.9 If the SOP involves production processes, the QA Manager will forward the SOP to the Production Supervisor for review. The Production Supervisor will review the SOP for practicality and feasibility within the production environment.

5.2.10 If the SOP involves Quality Control testing, the QA Manager will forward the SOP to the QC Inspector for review. The QC Inspector will review the SOP for accuracy, clarity, and completeness of quality control related procedures.

5.3 Approval

5.3.1 Once the QA Manager, Production Supervisor (if applicable), and QC Inspector (if applicable) have completed their reviews and are satisfied with the SOP, the QA Manager will forward the SOP to the Head of QA for final approval.

5.3.2 The Head of QA reviews the SOP to ensure that it meets all regulatory and internal requirements.

5.3.3 The Head of QA approves the SOP by signing and dating the approval section of the SOP.

5.3.4 The effective date of the SOP is 2025-01-01.

5.4 Distribution and Implementation

5.4.1 The QA Manager assigns a version number to the approved SOP (e.g., Version 1.0 for a new SOP, Version 2.0 for the first revision, etc.).

5.4.2 The QA Manager records the SOP in the SOP tracking log, including the SOP number, title, version number, effective date, and approval date.

5.4.3 The QA Manager distributes the approved SOP to the relevant departments and personnel. Distribution may be in electronic format (e.g., via email or network share) or in hard copy, as appropriate.

5.4.4 The QA Manager ensures that all personnel who are required to follow the SOP receive training on the new or revised SOP.

5.4.5 Training is documented on a Training Record Form, which includes the names of the trainees, the date of training, and the name of the trainer.

5.4.6 The QA Manager maintains a master list of SOPs and their current versions, and ensures that obsolete SOPs are removed from circulation and properly archived.

5.4.7 The QA Manager ensures that controlled copies are available at the point of use.

5.5 SOP Revision

5.5.1 The need for an SOP revision may arise from a change in process, equipment, regulatory requirements, or identified gaps in current procedures. A Change Control Request Form must be initiated and approved prior to the revision of any SOP.

5.5.2 The originating department designates a qualified individual to revise the SOP.

5.5.3 The designated individual obtains the current, approved version of the SOP from the QA Manager or the designated electronic location on the company network.

5.5.4 The designated individual makes the necessary revisions to the SOP, ensuring that the changes are clearly identified (e.g., using track changes or a revision history section).

5.5.5 The designated individual submits the revised SOP, along with the approved Change Control Request Form, to the originating department's supervisor or manager for review.

5.5.6 The revised SOP undergoes the same review and approval process as a new SOP, as described in sections 5.2 and 5.3.

5.5.7 The QA Manager assigns a new version number to the revised SOP.

5.5.8 The QA Manager updates the SOP tracking log with the new version number and effective date.

5.5.9 The QA Manager distributes the revised SOP to the relevant departments and personnel.

5.5.10 The QA Manager ensures that all personnel who are required to follow the revised SOP receive training on the changes.

5.5.11 The QA Manager removes the obsolete version of the SOP from circulation and properly archives it.

5.6 Periodic Review

5.6.1 All SOPs are reviewed at least every two years to ensure that they are still accurate, current, and effective.

5.6.2 The QA Manager coordinates the periodic review of SOPs, working with the originating departments to assess the need for revisions.

5.6.3 The review should consider any changes in process, equipment, regulatory requirements, or identified gaps in current procedures.

5.6.4 The review should also consider any feedback received from personnel who use the SOPs.

5.6.5 If revisions are necessary, the SOP is revised according to the procedure described in section 5.5.

5.6.6 If no revisions are necessary, the SOP is re-approved by the Head of QA, and the review date is recorded in the SOP tracking log.

6.0 POST-PROCEDURE ACTIVITIES

6.1 The QA Manager files the approved SOP and all supporting documentation (e.g., Change Control Request Form, Training Record Forms) in a secure, designated location.

6.2 The QA Manager updates the SOP tracking log to reflect the current status of the SOP.

6.3 The QA Manager ensures that all relevant personnel are trained on the new or revised SOP.

6.4 The QA Manager monitors the implementation of the SOP to ensure that it is being followed correctly and that it is effective.

6.5 The Head of QA conducts periodic audits of the SOP management system to ensure compliance with this SOP and with regulatory requirements.

7.0 SAFETY PRECAUTIONS

7.1 Always wear appropriate PPE when creating, reviewing, or implementing SOPs, as required by the procedures described in the SOPs being written.

7.2 Use caution when handling electronic equipment, such as computers and printers.

7.3 Ensure that the work area is clean and organized.

7.4 Report any safety hazards or incidents to the appropriate personnel.

7.5 All SOPs should include relevant safety precautions specific to the procedures described within the SOP.

7.6 MSDS sheets should be readily available for all chemicals used in the procedures described within the SOP.

8.0 APPROVALS

Prepared By: QA Specialist

Reviewed By: QA Manager

Approved By: Head of QA

Date:

Controlled Document Notice

Document Approval

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

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