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# 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

Version No.: 2.0

Effective Date: 2025-07-01

## 1.0 PURPOSE

This Standard Operating Procedure (SOP) defines the standardized process for creating, reviewing, approving, revising, and distributing all SOPs within NovaThera Pharmaceuticals Pvt. Ltd., Pune, India. This procedure ensures that all SOPs are consistently developed, implemented, and maintained to accurately reflect current Good Manufacturing Practices (cGMP) and comply with applicable regulatory requirements, including guidelines from the FDA, ICH (specifically ICH Q7, Q9, and Q10), and WHO GMP. The procedure promotes quality by design principles, risk management, and data integrity (ALCOA+ principles) throughout the SOP lifecycle, ultimately ensuring consistent execution of manufacturing processes, accurate documentation, and the production of safe and effective pharmaceutical products. It fosters a culture of continuous improvement within NovaThera Pharmaceuticals, guaranteeing the reliability and traceability of all operations impacting product quality.

## 2.0 SCOPE

This SOP applies to all departments and personnel involved in the creation, revision, review, approval, and distribution of Standard Operating Procedures (SOPs) within NovaThera Pharmaceuticals Pvt. Ltd., Pune, India. This includes, but is not limited to, SOPs pertaining to manufacturing, quality control,

quality assurance, engineering, facilities, materials management, and all other activities affecting the quality, safety, and efficacy of pharmaceutical products manufactured at NovaThera Pharmaceuticals. The scope encompasses all types of SOPs, including operational SOPs, equipment-related SOPs, analytical SOPs, and administrative SOPs. It covers all pharmaceutical products manufactured at NovaThera, from raw materials to finished goods, including tablets, capsules, liquids, and semi-solids. Excluded from this SOP are training documents, batch records (although their creation is often dictated by an SOP), and policies that do not directly describe a specific operational procedure. This SOP applies to both paper-based and electronic SOPs, including their storage, retrieval, and archiving. This SOP encompasses change control activities associated with SOP revisions and deviations related to SOP implementation.

## 3.0 RESPONSIBILITY

**QC Inspector: Responsible for reviewing SOPs to ensure the described procedures are accurate, clear, and aligned with current laboratory practices and analytical testing requirements. The QC Inspector is also responsible for verifying that SOPs include appropriate quality control checks and acceptance criteria, and for reporting any discrepancies or areas for improvement to the QA Manager. Specific duties include verifying test methods, sample handling procedures, and data recording practices. The QC Inspector will use pre-defined checklists and quality metrics, aiming for zero critical errors and a 95% compliance rate with established testing parameters as described in SOPs.**

**Production Supervisor: Responsible for ensuring that all production personnel are adequately trained on the relevant SOPs and that the SOPs are followed correctly during manufacturing operations. The Production Supervisor monitors adherence to SOPs, identifies any deviations, and initiates corrective actions as needed. This role has the authority to make minor adjustments to the procedure in consultation with the QA Manager to optimize workflow while maintaining compliance. They ensure that equipment is properly maintained and calibrated as per SOP requirements. Supervisory responsibilities include daily audits of production activities against SOPs, addressing deviations promptly and documenting any changes.**

**QA Manager: Responsible for overseeing the entire SOP lifecycle, including review, approval, implementation, and maintenance. The QA Manager ensures that all SOPs comply with applicable regulations and internal quality standards. The QA Manager facilitates the review process, ensures that all relevant departments are involved, and resolves any conflicts or discrepancies. This role also manages the change control process for SOP revisions and is responsible for investigating and addressing any deviations related to SOPs. They must guarantee that all SOPs are available to relevant personnel and archived appropriately. The QA Manager will monitor key performance indicators (KPIs) related to SOP compliance, such as the number of deviations related to SOPs, the timeliness of SOP revisions, and the effectiveness of SOP training.**

**Head of QA: Responsible for providing strategic oversight of the SOP management system. The Head of QA approves all new and revised SOPs, ensuring that they are aligned with the company's quality policy and regulatory requirements. The Head of QA acts as the primary liaison with regulatory agencies regarding SOP-related matters. They ensure that the SOP system is continuously improved to meet evolving regulatory expectations and industry best practices. This role ensures that adequate resources are available for SOP development, review, and training. They will conduct periodic audits of the SOP system to ensure its effectiveness and compliance.**

## 4.0 MATERIALS & EQUIPMENT

**PPE: Safety glasses (ANSI Z87.1 rated), laboratory coats (disposable, Level A), nitrile gloves (powder-free, non-sterile), and, where applicable, respiratory protection (N95 masks or powered air-purifying respirators (PAPRs) depending on the hazard assessment). Specific PPE requirements are detailed in the site-specific safety SOP (SOP-HS-001).**

**Equipment: Computer with internet access and access to the company's document management system, printer (laser printer, high resolution), scanner (flatbed scanner), SOP templates (electronic versions), change control forms (electronic and paper-based), deviation report forms (electronic and paper-based).**

**Documentation: SOP template (SOP-QA-001-Template), SOP tracking log (SOP-QA-001-Log), change control request form (CCF-001), deviation report form (DRF-001), training record form (TRF-001), risk assessment template (RAT-001), and relevant regulatory guidelines (FDA CFR Parts 210 & 211, ICH Q7, Q9, Q10, WHO GMP). All documents are controlled and managed within the company’s Electronic Document Management System (EDMS), ensuring version control and audit trails.**

Reagents/Chemicals: Not applicable.

## 5.0 PROCEDURE

### 5.1 Pre-Activity Preparation

#### 5.1.1 Identify the need for a new SOP or revision of an existing SOP. This can arise from changes in regulations, processes, equipment, materials, or from a deviation investigation. The need should be documented in the SOP tracking log (SOP-QA-001-Log).

Verification: The need for the SOP must be justified with supporting documentation, such as a change control request (CCF-001) or a deviation report (DRF-001).

#### 5.1.2 Assign a responsible person (role, not name) to draft the SOP or revision.

Verification: The assignment should be recorded in the SOP tracking log.

#### 5.1.3 Obtain the appropriate SOP template (SOP-QA-001-Template) from the company's document management system.

Verification: Ensure the correct version of the template is used by checking the template's version number against the document management system.

### 5.1.4 Conduct a preliminary risk assessment (using RAT-001) to identify potential hazards and risks associated with the procedure being documented. This assessment should consider safety, quality, and compliance aspects.

Verification: The risk assessment should be documented and reviewed by the QA Manager.

## 5.2 Drafting the SOP

### 5.2.1 Populate the SOP template with the required information, including the SOP title, SOP number, version number, effective date, purpose, scope, responsibilities, materials & equipment, procedure, post-activity procedures, safety precautions, quality control measures, documentation and records, deviations and corrective actions, training requirements, review and revision, and approvals. Use clear, concise, and unambiguous language.

Quality Checkpoint: Ensure the SOP title accurately reflects the procedure being described. Ensure the SOP number follows the company's SOP numbering convention.

### 5.2.2 Describe the procedure in a step-by-step manner, providing sufficient detail to allow a trained operator to perform the task correctly and consistently. Use action verbs and avoid passive voice. Include specific parameters, tolerances, and acceptance criteria where applicable.

Quality Checkpoint: Each step should be clear, concise, and measurable.

### 5.2.3 Incorporate relevant safety precautions and warnings throughout the procedure. Refer to site-specific safety SOPs where appropriate (e.g., SOP-HS-001 for general safety guidelines).

Quality Checkpoint: Ensure safety precautions are aligned with the risk assessment findings.

### 5.2.4 Include specific quality control measures at appropriate points in the procedure. These measures should include checks, tests, and inspections to ensure that the procedure is being performed correctly and that the results are within acceptable limits.

Quality Checkpoint: Quality control measures should be objective and measurable.

#### 5.2.5 Define the required documentation and records, including the forms and logs that need to be completed, and the location where the records should be stored.

Quality Checkpoint: Ensure documentation requirements are aligned with data integrity principles (ALCOA+).

#### 5.2.6 Include specific equipment codes (e.g., BLN-04 for blenders, TCP-01 for tablet press, SFT-02 for sifter) where applicable. Ensure equipment is referenced by its unique identifier and location.

Quality Checkpoint: Verify equipment codes against the equipment inventory log.

#### 5.2.7 Reference any other relevant SOPs or documents within the SOP.

Quality Checkpoint: Ensure that all referenced documents are the current approved versions.

### 5.3 Reviewing the SOP

#### 5.3.1 Submit the draft SOP to the QA Manager for review.

Verification: Document the submission date in the SOP tracking log.

#### 5.3.2 The QA Manager will distribute the draft SOP to relevant departments (e.g., Production, Quality Control, Engineering) for review.

Verification: Record the distribution list in the SOP tracking log.

#### 5.3.3 Reviewers should carefully examine the SOP for accuracy, clarity, completeness, and compliance with applicable regulations and internal quality standards. They should provide written comments and suggestions for improvement.

Quality Checkpoint: Reviewers should focus on the areas within their expertise.

#### 5.3.4 The QA Manager will compile all reviewer comments and forward them to the responsible person.

Verification: Ensure all comments are addressed.

**5.3.5 The responsible person will revise the SOP based on the reviewer comments. Any disagreements or unresolved issues should be discussed and resolved with the QA Manager.**

Quality Checkpoint: Document the rationale for any changes made to the SOP.

**5.4 In-Process Controls**

**5.4.1 During the SOP drafting and review stages, specific quality control checkpoints are implemented to ensure compliance with regulatory requirements and internal standards.**

**5.4.2 Verification of Accuracy: The QA Manager and relevant department representatives (QC, Production, Engineering) must verify that the SOP accurately reflects the current processes and equipment used. Any discrepancies must be resolved before approval. Acceptance Criteria: 100% accuracy in describing the procedures.**

**5.4.3 Clarity and Understandability Review: The SOP must be written in clear, concise language that is easily understood by all personnel who will be using it. A readability assessment should be conducted, using tools like the Flesch-Kincaid readability test. Acceptance Criteria: Readability score of 60 or higher (indicating it can be understood by personnel with a typical reading level).**

**5.4.4 Compliance with Regulatory Guidelines: The SOP must comply with all applicable regulatory guidelines, including those from the FDA, ICH (specifically ICH Q7, Q9, and Q10), and WHO GMP. A compliance checklist should be used to ensure that all relevant requirements are addressed. Acceptance Criteria: 100% compliance with all applicable regulatory guidelines.**

**5.4.5 Data Integrity Assessment: The SOP must include provisions to ensure the integrity of all data generated as a result of the procedure being performed. This includes requirements for data recording, storage, and retrieval. The ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, Available) must be followed. Acceptance Criteria: All data elements generated by the procedure must meet the ALCOA+ principles.**

**5.4.6 Risk Assessment Verification: The risk assessment conducted during the pre-activity preparation stage must be reviewed and verified to ensure that all potential hazards and risks have been identified and that appropriate controls are in place. Acceptance Criteria: All identified risks must be adequately mitigated by the controls described in the SOP.**

**5.4.7 Change Control and Deviation Management Procedures: The SOP must include procedures for managing changes and deviations related to the procedure being described. This includes requirements for documenting changes, investigating deviations, and implementing corrective and preventive actions (CAPA). Acceptance Criteria: Change control and deviation management procedures must be clearly defined and compliant with company policies.**

**5.5 Approving the SOP**

**5.5.1 Once the SOP has been revised to address all reviewer comments, the QA Manager will submit it to the Head of QA for approval.**

Verification: Document the submission date in the SOP tracking log.

**5.5.2 The Head of QA will review the SOP to ensure that it meets all requirements and that it is aligned with the company's quality policy and regulatory requirements.**

**5.5.3 Upon approval, the Head of QA will sign and date the SOP.**

Verification: The approval date should be clearly indicated on the SOP.

#### 5.5.4 The approved SOP will be assigned a unique version number and effective date.

Verification: Ensure the version number and effective date are correctly recorded in the SOP tracking log.

### 5.6 Distributing the SOP

#### 5.6.1 The QA Manager will distribute the approved SOP to all relevant departments and personnel.

Verification: Maintain a distribution list to track who has received the SOP.

#### 5.6.2 The SOP should be made available in both paper-based and electronic formats, as appropriate.

Verification: Ensure the SOP is accessible through the company's document management system.

#### 5.6.3 All personnel who are required to follow the SOP should be trained on its contents.

Verification: Training records should be maintained to document the training provided.

6.0 POST-ACTIVITY PROCEDURES

6.1 Data Review: The QA Manager (or designee) will review all data generated as a result of the SOP to ensure accuracy, completeness, and compliance with regulatory requirements and internal quality standards. Any discrepancies or anomalies should be investigated and resolved.

6.2 Equipment Cleaning: If the SOP involves the use of equipment, ensure that the equipment is cleaned and maintained according to the equipment's cleaning and maintenance SOP (e.g., SOP-ENG-001 for equipment cleaning). Document the cleaning and maintenance activities in the equipment logbook.

6.3 Documentation Completion: Ensure that all required forms and logs are completed accurately and completely. Review the completed documentation for any errors or omissions. Correct any errors and obtain the necessary signatures.

6.4 Record Storage: Store all completed documentation and records in accordance with the company's record retention policy. Electronic records should be stored in a secure electronic system with appropriate access controls and audit trails. Paper-based records should be stored in a secure, climate-controlled environment.

6.5 Performance Monitoring: The QA Manager will monitor the performance of the SOP to identify any areas for improvement. This may involve tracking deviations, conducting audits, and soliciting feedback

from personnel who use the SOP.

6.6 Reporting: Periodic reports will be generated to summarize the performance of the SOP and to identify any trends or issues that need to be addressed. These reports will be reviewed by the Head of QA and other relevant stakeholders.

## 7.0 SAFETY PRECAUTIONS

7.1 General Safety: All personnel must follow the company's general safety guidelines, as outlined in the site-specific safety SOP (SOP-HS-001).

7.2 Hazard Communication: All personnel must be trained on the hazards associated with the materials and equipment used in the procedure, as required by the company's hazard communication program.

7.3 PPE: All personnel must wear the appropriate personal protective equipment (PPE) as specified in Section 4.0.

7.4 Emergency Procedures: All personnel must be familiar with the company's emergency procedures, including evacuation routes, first aid procedures, and spill response procedures. Emergency contact information should be readily available.

7.5 Risk Assessment: A risk assessment should be conducted prior to performing the procedure to identify potential hazards and risks. The risk assessment should be documented and reviewed by the QA Manager. Mitigation measures should be implemented to reduce the risks to an acceptable level.

8.0 QUALITY CONTROL MEASURES

8.1 Quality Control Checks: Throughout the SOP lifecycle, specific quality control checks are implemented to ensure compliance with regulatory requirements and internal standards. These checks include:

8.1.1 Accuracy Verification: The QA Manager and relevant department representatives (QC, Production, Engineering) must verify that the SOP accurately reflects the current processes and equipment used. Any discrepancies must be resolved before approval.

8.1.2 Clarity and Understandability Review: The SOP must be written in clear, concise language that is easily understood by all personnel who will be using it.

8.1.3 Compliance with Regulatory Guidelines: The SOP must comply with all applicable regulatory guidelines, including those from the FDA, ICH (specifically ICH Q7, Q9, and Q10), and WHO GMP.

8.1.4 Data Integrity Assessment: The SOP must include provisions to ensure the integrity of all data generated as a result of the procedure being performed. This includes requirements for data recording, storage, and retrieval.

8.1.5 Risk Assessment Verification: The risk assessment conducted during the pre-activity preparation stage must be reviewed and verified to ensure that all potential hazards and risks have been identified and that appropriate controls are in place.

8.1.6 Change Control and Deviation Management Procedures: The SOP must include procedures for managing changes and deviations related to the procedure being described. This includes requirements for documenting changes, investigating deviations, and implementing corrective and preventive actions (CAPA).

8.2 Sampling Plans: Not applicable for this SOP.

8.3 Acceptance Criteria: Acceptance criteria for each quality control check should be clearly defined in the SOP. Examples of acceptance criteria include:

8.3.1 100% accuracy in describing the procedures.

8.3.2 Readability score of 60 or higher (indicating it can be understood by personnel with a typical reading level).

8.3.3 100% compliance with all applicable regulatory guidelines.

8.3.4 All data elements generated by the procedure must meet the ALCOA+ principles.

8.3.5 All identified risks must be adequately mitigated by the controls described in the SOP.

8.3.6 Change control and deviation management procedures must be clearly defined and compliant with company policies.

9.0 DOCUMENTATION AND RECORDS

9.1 Documentation Requirements: The following documentation is required for this SOP:

9.1.1 SOP template (SOP-QA-001-Template)

9.1.2 SOP tracking log (SOP-QA-001-Log)

9.1.3 Change control request form (CCF-001)

9.1.4 Deviation report form (DRF-001)

9.1.5 Training record form (TRF-001)

9.1.6 Risk assessment template (RAT-001)

9.1.7 Reviewer comments

9.1.8 Approved SOP

9.2 Record Retention: All records generated as a result of this SOP should be retained for a minimum of [Specify retention period – e.g., five years after the SOP is superseded or two years after product expiry, whichever is longer], in accordance with the company's record retention policy.

9.3 Data Integrity: All documentation and records must comply with the ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, Available). This includes:

9.3.1 Attributable: All data must be traceable to the person who generated it.

9.3.2 Legible: All data must be clear and readable.

9.3.3 Contemporaneous: All data must be recorded at the time it is generated.

9.3.4 Original: The original record must be retained.

9.3.5 Accurate: All data must be accurate and free from errors.

9.3.6 Complete: All data must be complete and include all relevant information.

9.3.7 Consistent: Data should be consistent across different records.

9.3.8 Enduring: Records should be stored in a way that ensures they are accessible and readable for the required retention period.

9.3.9 Available: Records should be readily available for review and audit.

9.4 Electronic Records: If electronic records are used, the system must comply with 21 CFR Part 11 requirements, including:

9.4.1 Audit trails: The system must have an audit trail that tracks all changes to the records.

9.4.2 Access controls: The system must have access controls to prevent unauthorized access to the records.

9.4.3 Electronic signatures: The system must support electronic signatures that are equivalent to handwritten signatures.

9.4.4 Validation: The system must be validated to ensure that it functions as intended.

10.0 DEVIATIONS AND CORRECTIVE ACTIONS

10.1 Deviation Handling: Any deviation from this SOP must be documented using the deviation report form (DRF-001). The deviation report should include a description of the deviation, the date and time it occurred, the personnel involved, the potential impact of the deviation, and the corrective actions taken.

10.2 Investigation: All deviations must be investigated to determine the root cause. The investigation should be conducted by the QA Manager (or designee) and should be documented in the deviation report.

10.3 Corrective and Preventive Actions (CAPA): Based on the investigation, appropriate corrective and preventive actions (CAPA) should be identified and implemented to prevent recurrence of the deviation. The CAPA should be documented in the deviation report.

10.4 CAPA Effectiveness Monitoring: The effectiveness of the CAPA should be monitored to ensure that it is achieving the desired results. The monitoring should be documented in the deviation report.

10.5 Escalation: If a deviation is significant or if the root cause cannot be determined, the deviation should be escalated to the Head of QA for further investigation and action.

11.0 TRAINING REQUIREMENTS

11.1 Personnel who are responsible for drafting, reviewing, approving, or distributing SOPs must be trained on this SOP.

11.2 Personnel who are required to follow this SOP must be trained on its contents.

11.3 Training should be conducted by a qualified trainer and should be documented using the training record form (TRF-001).

11.4 Training should include a review of the SOP, a discussion of the relevant regulatory requirements, and a demonstration of the procedures.

11.5 Personnel should be assessed to ensure that they have understood the training and are competent to perform the procedures.

11.6 Retraining should be conducted periodically to ensure that personnel remain up-to-date on the SOP and any changes to the regulatory requirements.

12.0 REVIEW AND REVISION

12.1 This SOP should be reviewed at least every two years, or more frequently if there are significant changes to the procedures or regulatory requirements.

12.2 The review should be conducted by the QA Manager (or designee) and should involve input from relevant departments.

12.3 Any revisions to the SOP must be approved by the Head of QA.

12.4 The version number and effective date of the SOP should be updated whenever it is revised.

12.5 Obsolete versions of the SOP should be archived and clearly marked as obsolete.

## 13.0 APPROVALS

**Prepared By: QA Specialist**

**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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