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Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
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Corrective and Preventive Action (CAPA) System

Category: Quality Assurance

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Quality Assurance

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1.0 PURPOSE

This procedure establishes a standardized system for identifying, documenting, evaluating, correcting, and preventing potential or actual deviations, discrepancies, errors, and failures within NovaThera Pharmaceuticals' pharmaceutical manufacturing processes, ensuring product quality, patient safety, and compliance with cGMP regulations. This CAPA system provides a structured approach to systematically investigate issues, determine root causes, implement effective corrective and preventive actions, and verify the effectiveness of those actions to prevent recurrence.

2.0 SCOPE

This SOP applies to all departments and personnel within NovaThera Pharmaceuticals Pvt. Ltd. involved in pharmaceutical manufacturing, packaging, testing, storage, and distribution. It covers all materials, products, equipment, processes, and systems that have a direct or indirect impact on product quality, patient safety, or regulatory compliance. This SOP is applicable to all deviations, complaints, out-of-specification (OOS) results, audit findings, and other quality-related events, regardless of the product or batch involved. This includes, but is not limited to, raw materials, in-process materials, finished products, equipment malfunctions, process deviations, documentation errors, and training deficiencies.

3.0 RESPONSIBILITY

QC Inspector: Responsible for identifying and reporting potential deviations or discrepancies observed during routine inspections and testing, and for performing follow-up testing to verify the effectiveness of implemented CAPA.

Production Supervisor: Responsible for identifying and reporting deviations or discrepancies occurring during production processes, implementing immediate corrective actions to contain the issue, and assisting in the investigation of root causes.

QA Manager: Responsible for overseeing the CAPA system, ensuring timely and effective investigation and resolution of issues, approving CAPA plans, monitoring CAPA progress, and verifying the effectiveness of implemented actions. The QA Manager also ensures that all CAPA-related documentation is complete and accurate.

Head of QA: Responsible for final approval of CAPA plans, ensuring adequate resources are allocated for CAPA implementation, and for trending CAPA data to identify systemic issues and opportunities for improvement. The Head of QA is also responsible for ensuring that the CAPA system is compliant with cGMP regulations and internal quality standards.

4.0 MATERIALS & EQUIPMENT

PPE: Safety glasses, laboratory coat, appropriate gloves (nitrile or latex depending on the material being handled), and any other PPE as determined by the relevant safety data sheet (SDS).

Equipment: Computer with internet access, printer, and relevant software for data analysis and documentation.

Documentation:

- CAPA Request Form (FRM-QA-007-01)
- CAPA Investigation Report (FRM-QA-007-02)
- CAPA Plan (FRM-QA-007-03)
- CAPA Effectiveness Verification Report (FRM-QA-007-04)
- Deviation Report (FRM-QA-001-01)
- Out-of-Specification (OOS) Investigation Report (FRM-QC-002-01)
- Complaint Log (REG-QA-003-01)
- Change Control Form (FRM-QA-006-01)
- Training Records (REG-HR-001-01)

5.0 PROCEDURE

5.1 CAPA Initiation

5.1.1 Any employee who identifies a potential deviation, discrepancy, complaint, OOS result, audit finding, or other quality-related event must immediately notify their supervisor and document the event on the appropriate form (e.g., Deviation Report, Complaint Log, OOS Investigation Report).

5.1.2 The Production Supervisor (for production-related issues), QC Inspector (for lab-related issues), or other designated personnel will complete the CAPA Request Form (FRM-QA-007-01) with a detailed description of the event, including the date, time, location, individuals involved, and any relevant observations.

5.1.3 The completed CAPA Request Form is submitted to the QA Manager for review and assessment.

5.1.4 The QA Manager reviews the CAPA Request Form to determine if a CAPA is warranted. The QA Manager considers the potential impact of the event on product quality, patient safety, and regulatory compliance.

5.1.5 If the QA Manager determines that a CAPA is not warranted, the reason for rejection is documented on the CAPA Request Form, and the form is filed accordingly. The originator of the CAPA request is notified of the decision.

5.1.6 If the QA Manager determines that a CAPA is warranted, a CAPA number is assigned, and the CAPA is officially initiated. The QA Manager assigns a CAPA owner (typically the department head or a designated representative) responsible for leading the investigation and implementing the CAPA.

5.2 CAPA Investigation

5.2.1 The CAPA owner forms an investigation team, as necessary, consisting of individuals with relevant expertise and knowledge of the process or system involved.

5.2.2 The investigation team conducts a thorough investigation to determine the root cause(s) of the event. The investigation may involve reviewing documentation, interviewing personnel, performing process simulations, conducting additional testing, and analyzing data.

5.2.3 The investigation team uses appropriate root cause analysis tools, such as the "5 Whys," Fishbone diagrams (Ishikawa diagrams), or Fault Tree Analysis, to systematically identify the underlying causes of the event.

5.2.4 The investigation team documents the investigation process, findings, and identified root cause(s) in the CAPA Investigation Report (FRM-QA-007-02). The report must include a clear and concise description of the event, the investigation methodology, the data analyzed, the conclusions reached, and the identified root cause(s).

5.2.5 If the investigation reveals that a batch is potentially affected, the QA Manager initiates a risk assessment to determine the impact on product quality and patient safety. This may involve recalling affected batches or performing additional testing to ensure product quality.

5.3 CAPA Plan Development

5.3.1 Based on the identified root cause(s), the CAPA owner develops a CAPA Plan (FRM-QA-007-03) that outlines the specific corrective and preventive actions to be taken to address the root cause(s) and prevent recurrence.

5.3.2 Corrective actions are actions taken to eliminate the existing deviation or problem. Preventive actions are actions taken to prevent the occurrence

of similar deviations or problems in the future.

5.3.3 The CAPA Plan must include the following information:

- Description of the corrective and preventive actions to be taken.
- Timeline for implementation of each action.
- Assignment of responsibility for implementing each action.
- Metrics for measuring the effectiveness of each action.
- Documentation requirements for each action.

5.3.4 The CAPA Plan is reviewed and approved by the QA Manager. The Head of QA provides final approval for significant CAPAs or those with a high potential impact on product quality or patient safety.

5.3.5 If the CAPA Plan involves changes to existing processes, procedures, or equipment, a Change Control request (FRM-QA-006-01) must be initiated and approved before implementing the changes.

5.4 CAPA Implementation

5.4.1 The CAPA owner ensures that the corrective and preventive actions outlined in the CAPA Plan are implemented according to the established timeline.

5.4.2 All actions must be documented thoroughly, including the date of implementation, the individuals involved, and any relevant observations.

5.4.3 The Production Supervisor ensures that any necessary training is provided to personnel affected by the changes implemented as part of the CAPA. Training records (REG-HR-001-01) must be maintained. For example, if the CAPA involves changes to the operating procedure for the BLN-04 blender, relevant personnel must be trained on the revised procedure.

5.4.4 The QC Inspector performs any necessary testing to verify that the implemented actions have been effective in addressing the root cause(s) and preventing recurrence. For example, if the CAPA involved an OOS result for tablet hardness, the QC Inspector performs re-testing of the affected batch and subsequent batches to ensure that the tablet hardness is within specifications.

5.5 CAPA Effectiveness Verification

5.5.1 After the corrective and preventive actions have been implemented, the CAPA owner, in conjunction with the QA Manager, conducts an effectiveness verification to determine if the actions have been successful in preventing recurrence.

5.5.2 The effectiveness verification may involve reviewing data, interviewing personnel, performing process simulations, conducting additional testing, and analyzing trends.

5.5.3 The effectiveness verification is documented in the CAPA Effectiveness Verification Report (FRM-QA-007-04). The report must include a clear and concise description of the effectiveness verification methodology, the data analyzed, the conclusions reached, and a statement regarding the effectiveness of the implemented actions.

5.5.4 If the effectiveness verification demonstrates that the actions have been effective, the CAPA is considered closed.

5.5.5 If the effectiveness verification demonstrates that the actions have not been effective, the CAPA is re-opened, and the CAPA owner initiates a new investigation to identify the reasons for the ineffectiveness and develop revised corrective and preventive actions.

5.6 CAPA Closure

5.6.1 The QA Manager reviews the CAPA file to ensure that all required documentation is complete and accurate.

5.6.2 The QA Manager approves the closure of the CAPA.

5.6.3 The CAPA file is archived according to the company's record retention policy.

5.7 CAPA Trending

5.7.1 The QA Manager periodically trends CAPA data to identify systemic issues and opportunities for improvement. The trending analysis may include identifying common root causes, recurring deviations, or areas where the CAPA system is not functioning effectively.

5.7.2 The results of the CAPA trending analysis are reported to the Head of QA and used to inform continuous improvement efforts.

5.7.3 For example, if the trending analysis reveals that a significant number of CAPAs are related to equipment malfunctions, the Head of QA may allocate additional resources for equipment maintenance and calibration. If the trending analysis reveals that a significant number of CAPAs are related to training deficiencies, the Head of QA may implement additional training programs.

6.0 POST-PROCEDURE ACTIVITIES

After the CAPA is closed, the QA Manager ensures that the CAPA data is entered into the CAPA tracking system. The Head of QA reviews the CAPA trending data on a quarterly basis to identify any systemic issues or areas for improvement. The QA Manager is responsible for scheduling and conducting periodic audits of the CAPA system to ensure its effectiveness and compliance with cGMP regulations.

7.0 SAFETY PRECAUTIONS

7.1 All personnel involved in the CAPA process must adhere to all relevant safety procedures and guidelines.

7.2 When investigating deviations involving hazardous materials, appropriate PPE must be worn, and all relevant safety precautions must be followed. Consult the SDS for specific handling and safety information.

7.3 When implementing corrective or preventive actions, ensure that all equipment is properly shut down and locked out before performing any maintenance or repairs.

7.4 Any changes to processes or procedures must be carefully evaluated for potential safety hazards, and appropriate controls must be implemented. For example, if the CAPA involves changes to the operating procedure for the SFT-02 sifter, ensure that all safety interlocks are functioning correctly before resuming operation.

7.5 Dispose of any waste materials generated during the CAPA process according to established waste disposal procedures.

8.0 APPROVALS

Prepared By: QA Officer

Reviewed By: QA Manager

Approved By: Head of QA

Date:

Controlled Document Notice

Document Approval

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