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Title:	Internal Audits / Self-Inspection	**Version:**	1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
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Internal Audits / Self-Inspection

Category: Quality Assurance

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Quality Assurance

Title: Internal Audits / Self-Inspection

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1.0 PURPOSE

This procedure establishes the methodology for conducting internal audits/self-inspections at NovaThera Pharmaceuticals Pvt. Ltd. to ensure compliance with current Good Manufacturing Practices (cGMP) and regulatory requirements for pharmaceutical manufacturing. This SOP ensures consistent and effective identification and correction of potential deficiencies, thereby maintaining a state of control and continuous improvement.

2.0 SCOPE

This SOP applies to all areas of NovaThera Pharmaceuticals Pvt. Ltd. involved in the manufacturing, packaging, testing, storage, and distribution of pharmaceutical products. This includes, but is not limited to, Production, Quality Control, Quality Assurance, Engineering, Warehouse, and Materials Management departments. It covers all products manufactured and packaged on site, including drug substances and drug products, regardless of batch size or dosage form. The procedure does not cover external audits conducted by regulatory agencies or customer audits, although the principles outlined herein may be applied in preparation for such audits.

3.0 RESPONSIBILITY

QC Inspector:

- Participates in internal audits as assigned by the QA Manager.
- Performs visual inspections and document reviews.
- Reports observations and deviations to the QA Manager.
- Assists in the verification of corrective actions.

Production Supervisor:

- Cooperates with auditors during the inspection of production areas.
- Ensures availability of personnel and documentation as required.
- Implements corrective actions identified during internal audits in a timely manner.
- Provides feedback to the QA Manager regarding the effectiveness of corrective actions.

QA Manager:

- Develops and maintains the internal audit schedule.
- Selects and trains qualified internal auditors.
- Leads and coordinates internal audits.
- Reviews audit reports and identifies trends.
- Tracks corrective and preventative actions (CAPA).
- Communicates audit findings to relevant departments.
- Ensures the effectiveness of the internal audit program.

Head of QA:

- Approves the internal audit schedule and audit reports.
- Provides oversight of the internal audit program.
- Ensures adequate resources are allocated for internal audits.
- Monitors the overall compliance status of the facility.
- Approves CAPA plans for critical audit findings.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses
- Lab coats
- Gloves (nitrile or appropriate material)
- Hairnets/beard covers (as required)
- Safety shoes

Equipment:

- Clipboards
- Pens (blue or black, non-smearing)
- Flashlight
- Measuring tape
- Camera (for documenting observations)
- Temperature and humidity monitoring devices (if required)
- Calibrated weighing balance (for raw material verification)

Documentation:

- Current Good Manufacturing Practices (cGMP) regulations
- Relevant Standard Operating Procedures (SOPs)
- Internal Audit Checklist (Form QA-010-01)
- Deviation Report Form (Form QA-005-01)
- Corrective and Preventative Action (CAPA) Form (Form QA-006-01)
- Training records
- Equipment maintenance logs
- Cleaning logs
- Batch production records (BPRs)
- Material Safety Data Sheets (MSDS)

5.0 PROCEDURE

5.1 Audit Scheduling and Preparation

5.1.1 The QA Manager shall develop an annual internal audit schedule based on a risk assessment of each area and process, considering factors such as past audit findings, regulatory changes, and production volume. The schedule shall be documented and approved by the Head of QA by December 1st of each year for the following year.

5.1.2 The QA Manager shall assign qualified auditors to conduct the audits based on their expertise and independence from the area being audited. Auditors must have successfully completed GMP training and internal auditor training.

5.1.3 The QA Manager shall notify the department to be audited at least two weeks prior to the scheduled audit date.

5.1.4 The QA Manager or designated auditor shall prepare an audit checklist (Form QA-010-01) based on the relevant SOPs, cGMP regulations, and the specific activities to be audited. The checklist should be tailored to the area being audited and include specific points to be verified. This includes referencing required documentation such as Batch Production Records and Equipment Logs.

5.1.5 The QA Manager shall ensure that the audit checklist is reviewed and approved prior to the audit.

5.2 Conducting the Audit

5.2.1 The assigned auditor shall conduct the audit according to the approved audit checklist (Form QA-010-01).

5.2.2 The auditor shall review relevant documentation, including SOPs, batch records, training records, equipment maintenance logs, cleaning logs, and material release records.

5.2.3 The auditor shall observe operations in progress, including adherence to SOPs, proper use of equipment, cleanliness of the area, and personnel practices.

5.2.4 The auditor shall interview personnel to assess their understanding of SOPs and cGMP requirements.

5.2.5 The auditor shall document all observations, including any deviations from SOPs or cGMP requirements, on the audit checklist. Objective evidence, such as photographs or copies of documents, should be collected to support the observations.

5.2.6 The auditor shall note the equipment identification code/number (e.g. BLN-04, TCP-01, SFT-02) if there are discrepancies related to equipment maintenance, calibration, or cleaning.

5.2.7 Any immediate safety hazards identified during the audit must be reported to the Production Supervisor and QA Manager immediately.

5.3 Audit Findings and Reporting

5.3.1 Following the audit, the auditor shall compile all observations and prepare an audit report summarizing the findings. The audit report shall include:

- The date and time of the audit
- The area audited
- The names of the auditors
- A summary of the observations, including any deviations from SOPs or cGMP requirements
- A risk assessment of each observation, classifying the severity as critical, major, or minor
- Recommendations for corrective actions

5.3.2 The auditor shall submit the audit report to the QA Manager within five working days of the audit.

5.3.3 The QA Manager shall review the audit report and assign responsibility for corrective actions to the appropriate department head (e.g., Production Supervisor, Engineering Manager).

5.3.4 The audit report shall be distributed to the Head of QA and the relevant department head.

5.4 Corrective and Preventative Action (CAPA)

5.4.1 The responsible department head shall develop a corrective action plan for each observation identified in the audit report. The corrective action plan shall include:

- A description of the corrective action to be taken
- The person responsible for implementing the corrective action
- The target completion date for the corrective action
- Preventative actions to avoid recurrence.

5.4.2 The corrective action plan shall be documented on a CAPA form (Form QA-006-01) and submitted to the QA Manager for review and approval.

5.4.3 The QA Manager shall review the corrective action plan to ensure that it adequately addresses the observation and is consistent with cGMP requirements.

5.4.4 Once the corrective action plan is approved, the responsible department head shall implement the corrective action within the specified timeframe.

5.4.5 The QA Manager shall verify the effectiveness of the corrective action by reviewing documentation, observing operations, or conducting follow-up audits. The verification must include objective evidence the corrective action was completed.

5.4.6 The closure of the CAPA will be documented on the CAPA form (Form QA-006-01) and approved by the QA Manager.

5.5 Follow-Up Audits

5.5.1 The QA Manager may schedule follow-up audits to verify the effectiveness of corrective actions or to assess the overall compliance status of a particular area.

5.5.2 Follow-up audits shall be conducted in the same manner as initial audits.

5.5.3 The results of follow-up audits shall be documented in an audit report and distributed to the relevant department heads.

5.6 Trend Analysis

5.6.1 The QA Manager shall conduct a periodic trend analysis of internal audit findings to identify recurring problems or systemic issues.

5.6.2 The trend analysis shall be used to identify areas for improvement in SOPs, training, or other aspects of the quality system.

5.6.3 The results of the trend analysis shall be reported to the Head of QA and used to inform the internal audit schedule.

6.0 POST-AUDIT ACTIVITIES

6.1 The QA Manager shall file the completed audit report, CAPA forms, and any supporting documentation in a designated audit file.

6.2 The QA Manager shall maintain a database of internal audit findings and CAPA activities.

6.3 The QA Manager shall present a summary of internal audit findings and CAPA activities to senior management on a quarterly basis.

6.4 The Production Supervisor shall ensure all personnel involved in the audited area are informed of the audit findings and any required changes to procedures or practices. The Supervisor shall maintain documented proof of this communication.

6.5 All records related to internal audits shall be retained in accordance with the company's record retention policy.

7.0 SAFETY PRECAUTIONS

7.1 Personnel conducting audits must adhere to all safety procedures and regulations applicable to the area being audited.

7.2 When entering production areas, auditors must wear appropriate PPE, including safety glasses, lab coats, gloves, and hairnets/beard covers.

7.3 Auditors must be aware of potential hazards in the area being audited, such as moving equipment, hazardous materials, and confined spaces.

7.4 Any unsafe conditions observed during the audit must be reported immediately to the Production Supervisor and QA Manager.

7.5 When reviewing documentation, auditors must handle documents carefully to avoid damage or loss.

7.6 If the auditor needs to operate any equipment for verification purposes (e.g., calibrated weighing balance), they must be trained and authorized to do so.

8.0 APPROVALS

Prepared By: QA Inspector

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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