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Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
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Line Clearance Procedure

Category: Quality Assurance

Standard Operating Procedure (SOP)

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1.0 PURPOSE

This procedure defines the requirements for performing and documenting line clearances in pharmaceutical manufacturing at NovaThera Pharmaceuticals to prevent mix-ups and cross-contamination during manufacturing, packaging, and labeling operations. It ensures that the work area is free from any materials, products, labels, documents, or equipment from previous operations before commencing a new operation.

2.0 SCOPE

This SOP applies to all production areas and equipment used in the manufacturing, packaging, and labeling of all pharmaceutical products at NovaThera Pharmaceuticals. It covers the line clearance procedures to be followed before the start of any new batch, product, or operation, including raw material dispensing, manufacturing, packaging, and labeling. This SOP applies to all personnel involved in the manufacturing, packaging, labeling, and quality control activities at NovaThera Pharmaceuticals.

3.0 RESPONSIBILITY

QC Inspector: Performs the line clearance inspection, verifies that all required steps have been completed, and documents the results in the line clearance checklist. Ensures that the area is free from previous batch materials, products, labels, and documentation.

Production Supervisor: Oversees the line clearance process, ensures that all personnel involved are properly trained, and verifies that the line clearance is performed according to this SOP. Initiates and signs the line clearance checklist after ensuring all steps are completed. Responsible for correcting any deficiencies identified during the line clearance inspection.

QA Manager: Reviews and approves the line clearance SOP and any revisions. Provides guidance and support for the implementation of the line clearance program. Responsible for investigating and resolving any deviations related to line clearance.

Head of QA: Provides final approval of the line clearance SOP and ensures its compliance with GMP regulations.

4.0 MATERIALS & EQUIPMENT

PPE: Safety glasses, gloves, lab coats, hairnets, shoe covers as required by the area.

Equipment: Cleaning materials (e.g., validated cleaning solutions, wipes, mops), vacuum cleaner (VAC-01), weighing balance (WBL-02), calibrated measuring devices, inspection lights.

Documentation: Line Clearance Checklist (Form QA-014), Batch Manufacturing Record (BMR), Batch Packaging Record (BPR), Equipment Logbooks, Cleaning Logs.

5.0 PROCEDURE

5.1 Pre-Line Clearance Preparation

5.1.1 The Production Supervisor schedules the line clearance to be performed.

5.1.2 The Production Supervisor ensures that all personnel involved in the line clearance are trained on this SOP.

5.1.3 The Production Supervisor ensures that the Line Clearance Checklist (Form QA-014) is available and properly filled out with the required information, including the batch number, product name, area, and date.

5.1.4 The Production Supervisor ensures that all required cleaning materials and equipment are available.

5.2 Removal of Previous Batch Materials

5.2.1 The Production Supervisor directs the removal of all materials, products, labels, documents, and equipment from the previous batch from the production area.

5.2.2 All raw materials, in-process materials, finished products, and rejected materials from the previous batch are removed from the area and returned to their designated storage locations.

5.2.3 All packaging materials (e.g., labels, cartons, inserts) from the previous batch are removed and returned to the packaging material storage area or destroyed as per the waste management procedure.

5.2.4 All documents related to the previous batch (e.g., Batch Manufacturing Record, Batch Packaging Record, logbooks) are removed from the area and returned to the document control center.

5.2.5 All tools, utensils, and equipment used in the previous batch are removed from the area and either cleaned and returned to their designated storage locations or sent for cleaning according to the equipment cleaning SOP.

5.3 Cleaning of the Production Area

5.3.1 The Production Supervisor ensures that the production area and all equipment are thoroughly cleaned according to the validated cleaning procedures.

5.3.2 All surfaces, including floors, walls, ceilings, and equipment, are cleaned using the appropriate cleaning agents and techniques.

5.3.3 The Production Supervisor verifies that the cleaning has been performed effectively and documents the cleaning in the equipment cleaning logbook.

5.3.4 The QC Inspector performs a visual inspection of the area to ensure that it is clean and free from any residues from the previous batch.

5.3.5 If any residues are found, the area is re-cleaned until it passes the visual inspection.

5.4 Equipment Inspection

5.4.1 The Production Supervisor ensures that all equipment to be used in the next batch is inspected for cleanliness and proper functioning.

5.4.2 The equipment is checked for any damage, wear, or malfunctions.

5.4.3 The Production Supervisor verifies that the equipment is properly calibrated and that the calibration certificates are up to date.

5.4.4 The equipment is checked to ensure that it is properly assembled and that all parts are in place.

5.4.5 The Production Supervisor documents the equipment inspection in the equipment logbook.

5.5 Verification of Line Clearance

5.5.1 The QC Inspector performs a detailed inspection of the production area and equipment to verify that the line clearance has been performed effectively.

5.5.2 The QC Inspector checks that all materials, products, labels, documents, and equipment from the previous batch have been removed.

5.5.3 The QC Inspector verifies that the area and equipment are clean and free from any residues.

5.5.4 The QC Inspector checks that the equipment is properly assembled, calibrated, and functioning correctly.

5.5.5 The QC Inspector compares the equipment setup to the requirements in the Batch Manufacturing Record or Batch Packaging Record for the next batch.

5.5.6 The QC Inspector records the results of the line clearance inspection in the Line Clearance Checklist (Form QA-014).

5.5.7 Any deficiencies identified during the line clearance inspection are immediately reported to the Production Supervisor.

5.6 Documentation of Line Clearance

5.6.1 The Production Supervisor and the QC Inspector sign and date the Line Clearance Checklist (Form QA-014) to certify that the line clearance has been completed successfully.

5.6.2 The Line Clearance Checklist is attached to the Batch Manufacturing Record or Batch Packaging Record for the next batch.

5.6.3 The Production Supervisor ensures that all relevant logbooks and records are updated with the line clearance information.

5.7 Line Clearance for Specific Equipment

5.7.1 Blenders (BLN-04): Ensure the blender is free from any residual powder or granules. Check the seals and gaskets for integrity. Verify that the blender is properly grounded.

5.7.2 Tablet Press (TCP-01): Ensure the tablet press is free from any broken tablets or residual powder. Inspect the dies and punches for damage or wear. Verify that the tablet press is properly lubricated.

5.7.3 Sifter (SFT-02): Ensure the sifter is free from any lumps or agglomerates. Inspect the mesh screen for damage or blockage. Verify that the sifter is properly aligned.

5.7.4 Weighing Balance (WBL-02): Ensure the weighing balance is clean and free from any spilled materials. Verify that the balance is properly calibrated and leveled.

6.0 POST-LINE CLEARANCE ACTIVITIES

6.1 The Production Supervisor authorizes the start of the next manufacturing, packaging, or labeling operation after successful completion and documentation of the line clearance.

6.2 The Production Supervisor ensures that all materials, products, labels, and documents required for the next operation are brought into the production area.

6.3 The Production Supervisor monitors the progress of the next operation to ensure that it is performed according to the Batch Manufacturing Record or Batch Packaging Record.

6.4 The Production Supervisor immediately addresses any deviations or issues that arise during the operation.

6.5 The Production Supervisor archives the Line Clearance Checklist along with the Batch Manufacturing Record or Batch Packaging Record.

6.6 The QA Manager periodically reviews completed Line Clearance Checklists for compliance and trends.

7.0 SAFETY PRECAUTIONS

7.1 Wear appropriate PPE, including safety glasses, gloves, lab coats, hairnets, and shoe covers, at all times during the line clearance process.

7.2 Handle cleaning agents according to the manufacturer's instructions and safety data sheets (SDS).

7.3 Use caution when handling equipment to avoid injuries.

7.4 Ensure that the production area is well-ventilated during cleaning.

7.5 Report any spills or accidents immediately to the Production Supervisor.

7.6 Follow all safety procedures and guidelines established by NovaThera Pharmaceuticals.

7.7 Avoid using damaged or malfunctioning equipment.

7.8 Ground all electrical equipment properly to prevent electrical hazards.

7.9 Use validated cleaning procedures to ensure the safety of the products and personnel.

7.10 Ensure proper disposal of waste materials according to the waste management procedure.

8.0 APPROVALS

Prepared By: Production Supervisor

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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