Document Type:	Standard Operating Procedure (SOP)	**SOP Code:**	SOP-WH-008
Title:	Shipping of Finished Goods	**Version:**	1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
Location:	Pune, India	**Review Date:**	2026-01-01

Shipping of Finished Goods

Category: Materials Management

Standard Operating Procedure (SOP)

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Department: Materials Management

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1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to define the procedure for the shipping of finished goods from NovaThera Pharmaceuticals Pvt. Ltd., Pune, India, ensuring compliance with Good Manufacturing Practices (GMP) and applicable regulatory guidelines. This SOP covers the receipt, storage, dispatch of finished goods, dispatch of finished products from unit to local export depot, and gate pass procedures.

2.0 SCOPE

This SOP applies to all personnel involved in the shipping of finished goods from the NovaThera Pharmaceuticals Pvt. Ltd. warehouse, including but not limited to Warehouse Operators, QC Inspectors, Production Supervisors, and the Materials Management department. This procedure applies to all finished pharmaceutical products manufactured by NovaThera Pharmaceuticals Pvt. Ltd.

3.0 RESPONSIBILITIES

3.1 Warehouse Operator: Responsible for the physical handling of finished goods, including receiving, storing, picking, packing, and loading for dispatch.

3.2 QC Inspector: Responsible for inspecting finished goods for quality, verifying batch numbers, expiry dates, and quantities against the dispatch documentation.

3.3 Production Supervisor: Responsible for ensuring that finished goods are properly packaged and labeled before being transferred to the warehouse.

3.4 QA Manager: Responsible for reviewing and approving the shipping documentation, ensuring compliance with GMP requirements, and investigating any deviations.

3.5 Head of QA: Responsible for the overall quality assurance of the shipping process, including approval of this SOP and any subsequent revisions.

4.0 DEFINITIONS

4.1 Finished Goods: Pharmaceutical products that have completed all manufacturing processes and are ready for distribution.

4.2 Batch Number: A unique identification number assigned to a specific batch of finished goods.

4.3 Expiry Date: The date after which a finished good is no longer considered suitable for use.

4.4 FIFO: First-In, First-Out, an inventory management method where the oldest stock is dispatched first.

4.5 FEFO: First-Expired, First-Out, an inventory management method where the stock with the earliest expiry date is dispatched first.

4.6 Dispatch Documentation: Documents such as delivery challans, invoices, and packing lists that accompany the finished goods during shipment.

4.7 GMP: Good Manufacturing Practices, guidelines that ensure products are consistently produced and controlled according to quality standards.

4.8 Local Export Depot: A designated location for temporary storage of finished goods awaiting export.

4.9 Gate Pass: A document authorizing the movement of materials in and out of the facility.

4.10 BLN-04: Specific code assigned to a designated battery operated stacker.

4.11 TCP-01: Specific code assigned to a designated temperature control printer

4.12 SFT-02: Specific code assigned to a designated safety fork truck

4.13 STK-01: Specific code assigned to a designated manual stacker.

5.0 PROCEDURE

5.1 Receipt of Finished Goods into the Warehouse

5.1.1 Upon arrival of finished goods from the production area, the Warehouse Operator shall verify the accompanying documentation (e.g., transfer note) against the physical goods.

5.1.2 The Warehouse Operator shall inspect the condition of the packaging for any damage or signs of tampering. Any discrepancies or damage shall be reported to the Production Supervisor and QA Manager immediately.

5.1.3 The QC Inspector shall sample the received finished goods according to approved sampling plans for identity and quality checks as required.

5.1.4 The Warehouse Operator shall record the receipt of finished goods in the warehouse inventory management system, including batch number, quantity, and expiry date.

5.1.5 Finished goods shall be moved to the designated storage location using appropriate material handling equipment (e.g., SFT-02, STK-01) following FIFO/FEFO principles.

5.1.6 The storage location shall be recorded in the warehouse inventory management system.

5.1.7 Temperature and humidity in the storage area shall be monitored continuously using calibrated monitoring devices. Records shall be maintained as per SOP-WH-001 (Environmental Monitoring). Any excursions from the specified limits shall be reported to the QA Manager and investigated.

5.2 Storage of Finished Goods

5.2.1 Finished goods shall be stored in a clean, dry, and well-ventilated area, protected from direct sunlight and extreme temperatures.

5.2.2 Storage areas shall be clearly labeled with product names, batch numbers, and expiry dates.

5.2.3 Aisle ways shall be kept clear to allow for easy access and movement of materials.

5.2.4 Regular inspections of the storage areas shall be conducted by the Warehouse Operator to ensure proper storage conditions and detect any signs of damage or deterioration.

5.2.5 Temperature and humidity data shall be reviewed regularly by the Warehouse Operator and QA Manager.

5.2.6 Pest control measures shall be implemented and documented as per SOP-WH-002 (Pest Control).

5.2.7 Any damaged or expired goods shall be quarantined and disposed of according to SOP-WH-003 (Waste Management).

5.2.8 Periodic inventory checks shall be conducted to verify the accuracy of the warehouse inventory management system.

5.3 Dispatch of Finished Goods

5.3.1 Upon receipt of a dispatch request, the Warehouse Operator shall retrieve the required finished goods from the storage location based on FIFO/FEFO principles.

5.3.2 The Warehouse Operator shall verify the batch number, quantity, and expiry date of the retrieved goods against the dispatch request.

5.3.3 The QC Inspector shall inspect the retrieved goods for quality and compliance with the dispatch request.

5.3.4 The finished goods shall be packed securely in appropriate packaging materials to prevent damage during transit.

5.3.5 Packaging materials shall be clean, dry, and free from any contaminants.

5.3.6 The packed goods shall be labeled clearly with the product name, batch number, quantity, expiry date, and shipping address.

5.3.7 The Warehouse Operator shall prepare the dispatch documentation, including delivery challans, invoices, and packing lists.

5.3.8 The QA Manager shall review and approve the dispatch documentation before shipment.

5.3.9 The Warehouse Operator shall load the finished goods onto the designated transport vehicle, ensuring proper handling and securing of the load.

5.3.10 The transport vehicle shall be clean and suitable for transporting pharmaceutical products.

5.3.11 The Warehouse Operator shall record the dispatch of finished goods in the warehouse inventory management system.

5.3.12 The Warehouse Operator shall ensure a copy of the dispatch documentation accompanies the shipment.

5.4 Dispatch of Finished Products from Unit to Local Export Depot

5.4.1 This section outlines the specific procedure for transferring finished goods from the manufacturing unit to a local export depot for subsequent

export activities.

5.4.2 The Production Supervisor shall notify the Warehouse Operator of the finished goods ready for transfer to the local export depot.

5.4.3 The Warehouse Operator shall verify the documentation (e.g., transfer note) against the physical goods, ensuring accuracy of product name, batch number, quantity, and expiry date.

5.4.4 The QC Inspector shall perform a random inspection of the finished goods to ensure they meet quality standards and are properly packaged for transit.

5.4.5 The finished goods shall be securely packed in appropriate shipping containers labeled with the product name, batch number, quantity, expiry date, destination (local export depot), and any specific handling instructions.

5.4.6 A delivery challan, prepared by the Warehouse Operator and approved by the QA Manager, shall accompany the shipment. The delivery challan shall include details such as product name, batch number, quantity, expiry date, and destination (local export depot).

5.4.7 The finished goods shall be transported to the local export depot using a designated transport vehicle. The transport vehicle shall be inspected to ensure it is clean, dry, and suitable for transporting pharmaceutical products.

5.4.8 During transit, temperature and humidity conditions inside the transport vehicle shall be monitored and recorded using calibrated temperature and humidity monitoring devices (TCP-01).

5.4.9 Upon arrival at the local export depot, the receiving personnel shall verify the shipment against the delivery challan and inspect the condition of the goods. Any discrepancies or damage shall be reported immediately to the QA Manager.

5.4.10 The Warehouse Operator shall maintain records of all shipments to the local export depot, including delivery challans, inspection reports, and temperature/humidity monitoring data.

5.5 Gate Pass Procedure

5.5.1 All materials, including finished goods, entering or leaving the NovaThera Pharmaceuticals Pvt. Ltd. facility must be accompanied by a valid gate pass.

5.5.2 The Warehouse Operator or designated personnel shall prepare the gate pass, providing details of the materials being shipped, including product name, batch number, quantity, and destination.

5.5.3 The gate pass must be authorized by the QA Manager before any materials can be moved.

5.5.4 The security personnel at the gate shall verify the gate pass against the physical goods before allowing entry or exit.

5.5.5 The security personnel shall maintain a record of all gate passes issued and received.

5.5.6 Any discrepancies or unauthorized movement of materials shall be reported immediately to the QA Manager and Head of Security.

5.6 Temperature/Humidity Monitoring

5.6.1 Temperature and humidity in the warehouse and during transportation shall be monitored continuously using calibrated monitoring devices.

5.6.2 Monitoring devices shall be calibrated according to SOP-QA-005 (Calibration of Equipment).

5.6.3 Temperature and humidity data shall be recorded at specified intervals (e.g., hourly, daily).

5.6.4 The Warehouse Operator shall review the temperature and humidity data regularly.

5.6.5 Any excursions from the specified limits shall be reported to the QA Manager and investigated.

5.6.6 Corrective actions shall be taken to address any temperature or humidity excursions, such as adjusting the HVAC system or relocating the affected goods.

5.7 Cleaning and Maintenance

5.7.1 The warehouse and storage areas shall be cleaned regularly according to SOP-WH-004 (Cleaning and Sanitation).

5.7.2 Cleaning materials shall be appropriate for use in a pharmaceutical environment and shall not contaminate the finished goods.

5.7.3 Cleaning activities shall be documented in a cleaning logbook.

5.7.4 Material handling equipment (e.g., forklifts, pallet jacks, STK-01, BLN-04, SFT-02) shall be maintained according to a preventive maintenance schedule.

5.7.5 Maintenance activities shall be documented in a maintenance logbook.

5.8 Line Clearance

5.8.1 After each shipping activity, a line clearance shall be performed to ensure that all materials and documentation related to the previous shipment have been removed.

5.8.2 The Warehouse Operator shall perform the line clearance, verifying that the area is free from any leftover materials, labels, or documentation.

5.8.3 The line clearance shall be documented in a line clearance checklist.

5.8.4 The QC Inspector shall review and approve the line clearance checklist.

6.0 DOCUMENTATION

6.1 The following documents shall be maintained as part of the shipping process:

- Receipt records
- Storage records
- Dispatch requests
- Delivery challans
- Invoices
- Packing lists
- Temperature and humidity monitoring records
- Cleaning logs
- Maintenance logs
- Gate pass records
- Inventory records
- Deviation reports (if any)
- Corrective action reports (if any)

6.2 All records shall be legible, accurate, and complete.

6.3 All records shall be stored securely and retained for the period specified in SOP-QA-001 (Document Control).

7.0 SAFETY PRECAUTIONS

7.1 All personnel involved in the shipping process shall wear appropriate personal protective equipment (PPE), including safety shoes, gloves, and eye protection.

7.2 Material handling equipment shall be operated by trained and authorized personnel only.

7.3 Safe lifting techniques shall be used to prevent injuries.

7.4 Emergency procedures shall be followed in case of accidents or spills.

7.5 The warehouse shall be equipped with fire extinguishers and other safety equipment.

7.6 Personnel shall be trained on fire safety and emergency evacuation procedures.

7.7 All electrical equipment must be grounded properly and regularly inspected for safety by qualified personnel.

8.0 DEVIATIONS

8.1 Any deviation from this SOP shall be documented in a deviation report.

8.2 The deviation report shall include a description of the deviation, the reason for the deviation, and the corrective action taken.

8.3 The deviation report shall be reviewed and approved by the QA Manager.

9.0 Training

9.1 All personnel performing this procedure must be trained according to the training SOP. Training records should be maintained according to the training SOP and document control SOP.

10.0 Annexures

10.1 Annexure 1: Gate Pass Template

10.2 Annexure 2: Dispatch Checklist

10.3 Annexure 3: Temperature Monitoring Log

END OF SOP

Document Approval

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

Document Control Information

Document ID: SOP-WH-008

Version: 1.0

Effective Date: 2025-01-01

Next Review Date: 2026-01-01

Generated by: NovaThera SOP Generator System