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Receipt of Raw Materials and Packaging Components

Category: Materials Management

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Materials Management

Title: Receipt of Raw Materials and Packaging Components

SOP No.: SOP-WH-001

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1.0 PURPOSE

1.1 This Standard Operating Procedure (SOP) defines the procedure for the receipt, identification, quarantine, sampling, storage, and release of raw materials, packaging materials, and finished products at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India. This SOP ensures compliance with Good Manufacturing Practices (GMP) and applicable regulatory guidelines. This SOP also outlines entry and exit procedures for the dispensing area.

2.0 SCOPE

2.1 This SOP applies to all personnel involved in the receipt, handling, sampling, storage, and release of raw materials, packaging materials, and finished products within the Materials Management Department, Quality Control Department, and Production Department at NovaThera Pharmaceuticals Pvt. Ltd. This includes the Warehouse Operator, QC Inspector, Production Supervisor, and QA Manager. It also covers the monitoring of temperature, relative humidity, and differential pressure within the warehouse and dispensing areas.

3.0 RESPONSIBILITIES

3.1 Warehouse Operator: Responsible for the physical receipt, verification of documentation, movement, storage, and issuance of raw materials, packaging materials, and finished products according to this SOP. The Warehouse Operator also monitors temperature and humidity, and ensures proper cleaning and maintenance of the warehouse.

3.2 QC Inspector: Responsible for the sampling of raw materials and packaging materials, as per the approved sampling plan, and for inspecting received materials for damage and compliance with specifications.

3.3 Production Supervisor: Responsible for requesting raw materials and packaging materials for production, and for ensuring the correct materials are used in the production process.

3.4 QA Manager: Responsible for the final approval of raw materials and packaging materials for use in production, reviewing all associated documentation, ensuring compliance with GMP, and overall monitoring of the SOP's effectiveness. The QA Manager also reviews temperature and humidity data.

4.0 DEFINITIONS

4.1 Raw Material: Any substance used in the manufacture of a pharmaceutical product, excluding packaging materials.

4.2 Packaging Material: Any material used to contain, protect, promote, and/or facilitate distribution of a pharmaceutical product. This includes primary, secondary, and tertiary packaging.

4.3 Finished Product: A pharmaceutical product that has completed all stages of the manufacturing process and is ready for distribution.

4.4 Quarantine: The status of materials isolated physically or by other effective means pending a decision on their subsequent approval or rejection.

4.5 Released: The status of materials that have been approved for use in production or for distribution.

4.6 Rejected: The status of materials that have been deemed unsuitable for use in production or for distribution.

4.7 FIFO: First In, First Out - An inventory management method in which the oldest inventory items are used first.

4.8 FEFO: First Expired, First Out - An inventory management method in which the inventory items with the earliest expiration dates are used first.

4.9 Dispensing Area: A designated area within the warehouse where raw materials are weighed and dispensed according to production requirements.

4.10 Differential Pressure: The pressure difference between two areas, used to control airflow and prevent contamination.

5.0 PROCEDURE

5.1 Receipt of Raw Materials and Packaging Components in Warehouse

5.1.1 The Warehouse Operator shall receive incoming shipments of raw materials and packaging components.

5.1.2 Upon receipt, the Warehouse Operator shall verify the following:

- The number of containers matches the packing list/delivery challan.
- The materials are clearly labeled with the supplier's name, material name, batch number, and quantity.
- The materials are not damaged or compromised during transit.
- The supplier is an approved supplier as per the Approved Vendor List.

5.1.3 If any discrepancies or damages are noted, the Warehouse Operator shall record the details on the Goods Received Note (GRN) and inform the QA Manager immediately. Photographic evidence of damage should be captured. The shipment should be quarantined pending investigation.

5.1.4 If the shipment is acceptable, the Warehouse Operator shall record the details in the Goods Received Note (GRN), including:

- Date of receipt
- Supplier's name and address
- Material name and code
- Batch number
- Quantity received
- Container details (e.g., number of drums, bags, cartons)
- Reference to the Purchase Order (PO) number
- Condition of the materials upon receipt

5.1.5 The Warehouse Operator shall assign a unique internal identification number to each received batch of raw materials and packaging components. This number should be recorded on the GRN and on a quarantine label attached to each container.

5.1.6 The GRN shall be signed and dated by the Warehouse Operator.

5.2 Receipt, Identification & Storage of Raw Materials

5.2.1 After verification and GRN completion, the Warehouse Operator shall move the received raw materials to the designated quarantine area using appropriate material handling equipment (e.g., forklift FLT-01, pallet jack PLJ-02).

5.2.2 The quarantine area shall be clearly marked and separated from the released material storage area.

5.2.3 Each container shall be labeled with the following information:

- Material name
- Internal identification number
- Batch number
- Quantity received
- Quarantine status
- Date of receipt

5.2.4 The Warehouse Operator shall update the inventory management system (IMS) with the details of the received raw materials, including the quantity, batch number, and location.

5.2.5 The QC Inspector shall be notified of the receipt of raw materials for sampling.

5.2.6 Sampling shall be conducted as per the approved sampling plan, SOP-QC-001.

5.2.7 After sampling, the QC Inspector shall affix a "Sampled" label to each container.

5.2.8 Samples shall be submitted to the Quality Control laboratory for testing.

5.2.9 The remaining raw materials shall remain in quarantine until the QC results are received and the materials are released by the QA Manager.

5.2.10 Upon receipt of the QC results, the QA Manager shall review the data and make a decision on the release or rejection of the raw materials.

5.2.11 If the raw materials are approved, the QA Manager shall update the IMS and authorize the Warehouse Operator to move the materials to the released material storage area. A "Released" label should be affixed.

5.2.12 If the raw materials are rejected, the QA Manager shall update the IMS and initiate the rejection procedure as per SOP-QA-002. The Warehouse Operator shall move the rejected materials to the designated rejected material storage area. A "Rejected" label should be affixed.

5.2.13 Storage of released raw materials shall be in accordance with the material's storage requirements (e.g., temperature, humidity, light sensitivity).

5.2.14 Raw materials shall be stored using the FIFO or FEFO principle, as appropriate.

5.2.15 Storage areas shall be clean, dry, and well-ventilated. Regular cleaning and maintenance shall be performed as per SOP-WH-005.

5.3 Receipt, Handling and Storage of Packing Materials

5.3.1 The procedure for receipt, identification, quarantine, and sampling of packaging materials is the same as for raw materials, as described in sections 5.1 and 5.2.

5.3.2 Packaging materials shall be stored in a dedicated area, separate from raw materials and finished products.

5.3.3 Packaging materials shall be protected from damage and contamination.

5.3.4 Specific storage conditions (e.g., temperature, humidity) shall be maintained as per the material's specifications.

5.3.5 Printed packaging materials shall be stored in a secure area to prevent unauthorized access.

5.3.6 Returned unused packaging materials from production should be handled as per SOP-PR-008 for reconciliation.

5.4 Receipt, storage and dispatch of Finished Products

5.4.1 Finished products received from the Production Department shall be accompanied by a batch manufacturing record (BMR).

5.4.2 The Warehouse Operator shall verify the quantity of finished products received against the BMR.

5.4.3 The finished products shall be visually inspected for any damage or defects.

5.4.4 The finished products shall be assigned a unique internal identification number and moved to the quarantine area.

5.4.5 A request for release shall be submitted to the QA Manager along with the BMR.

5.4.6 The QA Manager shall review the BMR and approve the release of the finished products if all specifications are met.

5.4.7 Upon release, the Warehouse Operator shall move the finished products to the released product storage area.

5.4.8 Finished products shall be stored in accordance with the product's storage requirements (e.g., temperature, humidity, light sensitivity).

5.4.9 Finished products shall be dispatched to customers or distributors as per the dispatch instructions.

5.4.10 Dispatch shall be documented in the dispatch record, including the date of dispatch, quantity dispatched, and destination.

5.4.11 FIFO or FEFO principles shall be applied to the dispatch of finished products.

5.5 Entry and Exit Procedure For Dispensing Area

5.5.1 Access to the dispensing area shall be restricted to authorized personnel only.

5.5.2 Personnel entering the dispensing area shall wear appropriate personal protective equipment (PPE), including cleanroom gowns, gloves, masks, and shoe covers.

5.5.3 Before entering the dispensing area, personnel shall remove any jewelry, watches, or other personal items that could contaminate the materials.

5.5.4 The dispensing area shall be cleaned and sanitized before and after each dispensing operation, as per SOP-WH-006.

5.5.5 All materials entering the dispensing area shall be cleaned and disinfected before entry.

5.5.6 The dispensing process shall be conducted in a manner that prevents cross-contamination.

5.5.7 All dispensing equipment shall be calibrated and maintained as per SOP-EQ-001.

5.5.8 After dispensing, all materials shall be properly labeled and returned to the appropriate storage location.

5.5.9 Personnel exiting the dispensing area shall remove their PPE and dispose of it properly.

5.5.10 The dispensing area shall be visually inspected after each dispensing operation to ensure that it is clean and free of debris.

5.5.11 Logbooks (LOG-DA-001) must be maintained for all activities performed in the dispensing area, including entry/exit times, cleaning, equipment usage, and dispensing details.

5.6 Monitoring of Temperature Relative Humidity and Differential Pressure

5.6.1 Temperature and relative humidity shall be monitored continuously in the warehouse and dispensing area using calibrated temperature and humidity sensors (THS-01 to THS-10).

5.6.2 Temperature and humidity data shall be recorded at least twice daily, or more frequently if required, on temperature and humidity monitoring charts (FMT-TH-001).

5.6.3 Differential pressure between the dispensing area and surrounding areas shall be monitored continuously using calibrated differential pressure sensors (DPS-01 and DPS-02).

5.6.4 Differential pressure data shall be recorded daily on differential pressure monitoring charts (FMT-DP-001).

5.6.5 The acceptable temperature, humidity, and differential pressure ranges shall be defined in the material specifications and facility SOPs.

5.6.6 Any deviations from the acceptable ranges shall be reported to the QA Manager immediately.

5.6.7 Corrective actions shall be taken to restore the temperature, humidity, and differential pressure to the acceptable ranges. The corrective actions shall be documented in the deviation report (FMT-QA-005).

5.6.8 Temperature and humidity sensors and differential pressure sensors shall be calibrated regularly as per the calibration schedule (SOP-EQ-002). Calibration records shall be maintained.

5.7 Cleaning and Maintenance

5.7.1 The warehouse and dispensing area shall be cleaned regularly to prevent the accumulation of dust, debris, and other contaminants.

5.7.2 Cleaning shall be performed using approved cleaning agents and procedures as per SOP-WH-005.

5.7.3 A cleaning schedule shall be established and followed to ensure that all areas are cleaned regularly.

5.7.4 Cleaning records shall be maintained, including the date of cleaning, the cleaning agents used, and the person who performed the cleaning.

5.7.5 Material handling equipment (e.g., forklifts, pallet jacks) shall be maintained regularly to ensure that they are in good working order.

5.7.6 Maintenance records shall be maintained for all equipment.

5.8 Line Clearance

5.8.1 Before and after each dispensing operation, a line clearance shall be performed to ensure that the area is free of any materials from the previous operation.

5.8.2 The line clearance shall be documented on a line clearance checklist (FMT-LC-001).

5.8.3 The line clearance checklist shall be signed and dated by the person who performed the line clearance.

6.0 SAFETY PRECAUTIONS

6.1 All personnel shall wear appropriate personal protective equipment (PPE) when handling raw materials, packaging materials, and finished products.

6.2 Appropriate PPE includes safety glasses, gloves, masks, and safety shoes.

6.3 Personnel shall be trained on the proper handling of hazardous materials.

6.4 Material Safety Data Sheets (MSDS) shall be readily available for all hazardous materials.

6.5 Spill kits shall be available in the warehouse and dispensing area.

6.6 All spills shall be cleaned up immediately and reported to the QA Manager.

6.7 Fire extinguishers shall be readily available in the warehouse and dispensing area.

6.8 Personnel shall be trained on the proper use of fire extinguishers.

6.9 Emergency contact information shall be posted in the warehouse and dispensing area.

6.10 Ensure proper ventilation in the warehouse and dispensing area.

6.11 Observe all safety regulations when operating material handling equipment like forklifts (FLT-01) and stackers (STK-01).

7.0 ENVIRONMENTAL CONTROLS

7.1 The warehouse and dispensing area shall be maintained at a temperature and humidity that is suitable for the storage of raw materials, packaging materials, and finished products.

7.2 The warehouse and dispensing area shall be well-ventilated to prevent the accumulation of dust and other contaminants.

7.3 The warehouse and dispensing area shall be protected from pests and rodents. Pest control measures shall be implemented and documented.

7.4 Waste materials shall be disposed of properly as per environmental regulations.

7.5 Cleaning materials should be environmentally friendly where possible.

8.0 DOCUMENTATION

8.1 The following documents shall be maintained as part of this SOP:

- Goods Received Note (GRN)
- Material Safety Data Sheets (MSDS)
- Sampling plan (SOP-QC-001)
- QC test results
- Inventory management system (IMS) records
- Temperature and humidity monitoring charts (FMT-TH-001)
- Differential pressure monitoring charts (FMT-DP-001)
- Cleaning schedule
- Cleaning records
- Calibration records (SOP-EQ-002)
- Line clearance checklist (FMT-LC-001)
- Deviation reports (FMT-QA-005)
- Batch Manufacturing Record (BMR)
- Dispatch record
- Approved Vendor List
- Logbooks (LOG-DA-001)
- Training records for personnel involved in the process.

8.2 All documents shall be accurate, legible, and complete.

8.3 All documents shall be stored in a secure location.

8.4 All documents shall be retained for the period specified in the document retention policy.

9.0 TRAINING

9.1 All personnel involved in the receipt, handling, sampling, storage, and release of raw materials, packaging materials, and finished products shall be trained on this SOP.

9.2 Training shall be conducted by a qualified trainer.

9.3 Training records shall be maintained for all personnel.

9.4 Refresher training shall be conducted periodically.

10.0 ABBREVIATIONS

10.1 SOP: Standard Operating Procedure

10.2 GMP: Good Manufacturing Practices

10.3 QA: Quality Assurance

10.4 QC: Quality Control

10.5 GRN: Goods Received Note

10.6 IMS: Inventory Management System

10.7 FIFO: First In, First Out

10.8 FEFO: First Expired, First Out

10.9 PPE: Personal Protective Equipment

10.10 MSDS: Material Safety Data Sheet

10.11 BMR: Batch Manufacturing Record

10.12 FLT-01: Forklift Identification Code

10.13 PLJ-02: Pallet Jack Identification Code

10.14 TCP-01: Temperature Control Probe Identification Code

10.15 SFT-02: Safety Footwear Type 2 Identification Code

10.16 STK-01: Stacker Identification Code

10.17 THS: Temperature Humidity Sensor

10.18 DPS: Differential Pressure Sensor

11.0 ATTACHMENTS

11.1 FMT-TH-001: Temperature and Humidity Monitoring Chart

11.2 FMT-DP-001: Differential Pressure Monitoring Chart

11.3 FMT-LC-001: Line Clearance Checklist

11.4 FMT-QA-005: Deviation Report

11.5 LOG-DA-001: Dispensing Area Logbook

12.0 REVISION HISTORY

Version No.	Effective Date	Changes Made	Reason for Change
1.0	2025-01-01	Initial Release	New SOP

Document Approval

Role	Name	Signature	Date
Prepared by:	_____	_____	_____
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