Document Type:	Standard Operating Procedure (SOP)	**SOP Code:**	SOP-WH-006
Title:	Inventory Management and Stock Control (FIFO/FEFO)	**Version:**	1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
Location:	Pune, India	**Review Date:**	2026-01-01

Inventory Management and Stock Control (FIFO/FEFO)

Category: Materials Management

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Materials Management

Title: Inventory Management and Stock Control (FIFO/FEFO)

SOP No.: SOP-WH-006

Version No.: 1.0

Effective Date: 2025-01-01

1.0 PURPOSE

1.1 The purpose of this Standard Operating Procedure (SOP) is to define the procedures for managing inventory and controlling stock levels of all raw materials, packaging materials, and other materials stored within the NovaThera Pharmaceuticals Pvt. Ltd. warehouse, ensuring compliance with Good Manufacturing Practices (GMP) and regulatory requirements. This SOP outlines procedures for receiving, storing, issuing, and tracking materials, emphasizing First-In, First-Out (FIFO) and First-Expired, First-Out (FEFO) principles to maintain material quality and prevent obsolescence.

2.0 SCOPE

2.1 This SOP applies to all personnel involved in the receipt, storage, issuance, and control of materials within the Materials Management department of NovaThera Pharmaceuticals Pvt. Ltd., including Warehouse Operators, QC Inspectors, Production Supervisors, and other authorized personnel. This SOP covers all materials stored in the warehouse, including raw materials, packaging materials, labels, printed materials, and any other materials used in the manufacturing process.

3.0 RESPONSIBILITIES

3.1 Warehouse Operator: Responsible for the physical receipt, storage, issuance, and movement of materials within the warehouse, adhering to FIFO/FEFO principles and recording all transactions accurately. Responsible for maintaining the cleanliness and organization of the warehouse. Operates equipment such as forklifts (FLK-01), stackers (STK-01), and pallet jacks (PLJ-02) safely and according to SOPs.

3.2 QC Inspector: Responsible for inspecting incoming materials for quality and compliance with specifications, sampling materials for testing, and releasing or rejecting materials based on QC results.

3.3 Production Supervisor: Responsible for requesting materials from the warehouse for production, ensuring that the correct materials are requested and used, and returning any unused materials to the warehouse with proper documentation.

3.4 QA Manager: Responsible for reviewing and approving this SOP, ensuring compliance with GMP and regulatory requirements, and conducting audits to verify adherence to this SOP. Responsible for investigating any deviations from this SOP and implementing corrective and preventive actions (CAPA).

3.5 Head of QA: Responsible for the overall quality assurance system and ensuring that all SOPs are compliant with GMP and regulatory requirements.

4.0 DEFINITIONS

4.1 FIFO (First-In, First-Out): A method of inventory management in which the oldest stock is used first.

4.2 FEFO (First-Expired, First-Out): A method of inventory management in which the stock with the earliest expiration date is used first.

4.3 Material Stock Register: A record used to track the quantity, location, and status of all materials stored in the warehouse.

4.4 Quarantine: The status of materials that are awaiting QC inspection and release.

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

4.6 Rejected: The status of materials that do not meet quality standards and cannot be used in production.

4.7 Batch Number: A unique identifier assigned to a specific quantity of material produced in a single manufacturing run.

4.8 Expiration Date: The date after which a material is no longer considered suitable for use.

4.9 Certificate of Analysis (COA): A document that provides the results of testing performed on a material.

4.10 Deviation: Any departure from approved procedures or specifications.

4.11 CAPA: Corrective and Preventive Action, a systematic process for identifying and eliminating the root causes of deviations and preventing their recurrence.

4.12 Material Safety Data Sheet (MSDS): Now referred to as Safety Data Sheet (SDS), a document that provides information on the potential hazards of a material and how to handle it safely.

4.13 Environmental Monitoring System (EMS): A system used to monitor and control environmental conditions within the warehouse, such as temperature and humidity.

4.14 Line Clearance: The process of removing all materials from a production line before starting a new production run.

4.15 Dispensing Booth: A controlled environment used for weighing and dispensing materials for production.

4.16 WMS: Warehouse Management System

5.0 PROCEDURE

5.1 Receiving Materials

5.1.1 Upon arrival of materials at the warehouse receiving area, the Warehouse Operator shall verify the delivery against the purchase order (PO) and packing list.

5.1.2 The Warehouse Operator shall visually inspect the materials for any damage or discrepancies. Any damage or discrepancies shall be documented on the receiving report.

5.1.3 The Warehouse Operator shall record the date of receipt, material name, supplier, batch number, quantity, and any other relevant information in the Material Stock Register (either physical or WMS).

5.1.4 The Warehouse Operator shall assign a unique identification number to each received item and attach a corresponding label.

5.1.5 The materials shall be moved to the quarantine area and clearly labeled as "QUARANTINED." Equipment used may include pallet jacks (PLJ-02).

5.1.6 The Warehouse Operator shall notify the QC Inspector to sample the materials for testing.

5.2 QC Inspection and Release

5.2.1 The QC Inspector shall sample the quarantined materials according to the approved sampling plan.

5.2.2 The QC Inspector shall perform the required tests on the samples and record the results in the QC testing record.

5.2.3 If the materials meet the required specifications, the QC Inspector shall release the materials and update the Material Stock Register (or WMS) accordingly.

5.2.4 If the materials do not meet the required specifications, the QC Inspector shall reject the materials and notify the QA Manager.

5.2.5 Rejected materials shall be clearly labeled as "REJECTED" and moved to the designated rejected materials area.

5.3 Storage of Materials

5.3.1 Released materials shall be stored in the designated storage locations according to the material storage map.

5.3.2 Materials shall be stored in a manner that prevents damage or contamination.

5.3.3 Temperature and humidity in the storage areas shall be monitored and recorded daily, using calibrated temperature and humidity monitoring devices (THM-01, THM-02). Records shall be reviewed by the Head of QA weekly. Excursions outside of the specified ranges (e.g., 20-25°C and 40-60% RH) must be immediately reported to the QA Manager and investigated.

5.3.4 FIFO/FEFO principles shall be strictly followed when storing materials. The Warehouse Operator, utilizing equipment such as forklifts (FLK-01) and stackers (STK-01), shall ensure that older materials are stored in front of newer materials.

5.3.5 Hazardous materials shall be stored in designated areas with appropriate safety precautions, adhering to SDS guidelines.

5.3.6 The warehouse layout is detailed in document LAY-001 and the storage location of materials is recorded in the WMS.

5.4 Issuance of Materials

5.4.1 Production Supervisor shall submit a material request form to the warehouse, specifying the materials required, quantity, batch number, and production order number.

5.4.2 The Warehouse Operator shall verify the material request form against the production schedule.

5.4.3 The Warehouse Operator shall select the materials for issuance according to FIFO/FEFO principles, ensuring that the materials with the earliest expiration dates are issued first.

5.4.4 The Warehouse Operator shall record the issuance of materials in the Material Stock Register (or WMS), including the date, quantity, batch number, and production order number.

5.4.5 The materials shall be transferred to the production area, along with the corresponding COA (if applicable).

5.5 Return of Unused Materials

5.5.1 Any unused materials remaining after production shall be returned to the warehouse with a return material form.

5.5.2 The Warehouse Operator shall verify the returned materials against the return material form and inspect the materials for any damage or contamination.

5.5.3 If the materials are in good condition, the Warehouse Operator shall return them to the designated storage locations and update the Material Stock Register (or WMS) accordingly.

5.5.4 If the materials are damaged or contaminated, the Warehouse Operator shall notify the QC Inspector for evaluation.

5.6 Inventory Reconciliation

5.6.1 A physical inventory count shall be conducted on a periodic basis (e.g., monthly, quarterly, annually) to reconcile the physical inventory with the Material Stock Register (or WMS) records.

5.6.2 Any discrepancies between the physical inventory and the Material Stock Register (or WMS) records shall be investigated and resolved.

5.6.3 The results of the inventory reconciliation shall be documented and reviewed by the QA Manager.

5.6.4 Cycle counts will be conducted on a weekly basis for high-value items.

5.7 Flow of Materials

5.7.1 The flow of materials within the warehouse shall be unidirectional, from the receiving area to the quarantine area, then to the released storage area, and finally to the issuance area.

5.7.2 The flow of materials shall be designed to minimize the risk of cross-contamination and ensure proper segregation of materials.

5.7.3 Material movement will be tracked using the WMS and physical logs.

5.8 Reconciliation of Raw and Packing Materials

5.8.1 Raw and packing materials issued to production are reconciled after each batch. This includes reconciliation of labels, printed materials and other packing materials.

5.8.2 A reconciliation report is prepared by the Production Supervisor and reviewed by the QA Manager.

5.8.3 Discrepancies are investigated, and corrective actions implemented.

5.9 Entry in Material Stock Register

5.9.1 All material movements (receipt, release, issuance, return, adjustments) are recorded in the Material Stock Register (or WMS) immediately.

5.9.2 Entries include date, material name, batch number, quantity, supplier, QC status, and any relevant comments.

5.9.3 The Material Stock Register (or WMS) is reviewed periodically by the Head of QA to ensure accuracy and completeness.

5.10 Physical Verification Handling of Excess and Shortages of Materials

5.10.1 Excess materials found during physical verification are investigated to determine the cause. The excess materials are properly labeled, recorded, and stored. The Material Stock Register (or WMS) is updated.

5.10.2 Shortages of materials found during physical verification are investigated to determine the cause. The shortage is documented, and corrective actions are implemented. The Material Stock Register (or WMS) is updated.

5.10.3 Any adjustments to the Material Stock Register (or WMS) are approved by the QA Manager.

5.11 Line Clearance Procedure

5.11.1 Before the start of a new production run, a thorough line clearance shall be performed to ensure that all materials from the previous production run have been removed.

5.11.2 The Production Supervisor shall inspect the production line and verify that it is free of any materials, documents, or equipment from the previous production run.

5.11.3 The line clearance shall be documented and signed off by the Production Supervisor.

5.11.4 The line clearance checklist (LCL-001) must be completed before the start of each production run.

5.12 Dispensing Booth Operations

5.12.1 Materials are dispensed in a controlled dispensing booth to ensure accuracy and prevent contamination.

5.12.2 The dispensing booth is cleaned and sanitized before and after each use according to SOP-CL-005.

5.12.3 The weighing equipment (e.g., TCP-01) is calibrated regularly.

5.12.4 Only authorized personnel are allowed to operate the dispensing booth.

5.13 Temperature and Humidity Monitoring

5.13.1 Temperature and humidity in the warehouse are monitored continuously using calibrated temperature and humidity monitoring devices (THM-01, THM-02).

5.13.2 The temperature and humidity readings are recorded at least twice daily.

5.13.3 If the temperature or humidity exceeds the specified limits, corrective actions are taken immediately, such as adjusting the HVAC system or using dehumidifiers.

5.13.4 The temperature and humidity records are reviewed by the Head of QA weekly.

5.14 Cleaning and Maintenance

5.14.1 The warehouse is cleaned regularly according to a documented cleaning schedule (CLS-001).

5.14.2 Cleaning materials are appropriate for pharmaceutical use and do not contaminate the materials stored in the warehouse.

5.14.3 Cleaning records are maintained.

5.14.4 Equipment such as forklifts (FLK-01), stackers (STK-01), and pallet jacks (PLJ-02) are maintained according to a preventative maintenance schedule (PMS-001).

6.0 DOCUMENTATION

6.1 The following documents shall be maintained:

- Purchase Orders

- Packing Lists
- Receiving Reports
- Material Stock Register (or WMS records)
- QC Testing Records
- Certificates of Analysis (COAs)
- Material Request Forms
- Return Material Forms
- Inventory Reconciliation Reports
- Temperature and Humidity Records
- Cleaning Records
- Equipment Maintenance Records
- Deviation Reports
- CAPA Reports
- Line Clearance Checklists
- Calibration Records
- Training Records

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

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

7.0 SAFETY PRECAUTIONS

7.1 All personnel shall follow safety procedures when handling materials, including wearing appropriate personal protective equipment (PPE) such as safety glasses, gloves, and safety shoes.

7.2 Hazardous materials shall be handled according to the SDS.

7.3 Equipment such as forklifts (FLK-01), stackers (STK-01), and pallet jacks (PLJ-02) shall be operated safely and according to the manufacturer's instructions and relevant SOPs. Only trained and authorized personnel are permitted to operate this equipment.

7.4 Fire safety equipment shall be readily available and maintained in good working order.

7.5 Emergency procedures shall be established and communicated to all personnel.

8.0 ENVIRONMENTAL CONTROLS

8.1 The warehouse shall be maintained in a clean and orderly condition to prevent contamination of materials.

8.2 Temperature and humidity shall be controlled to ensure the stability of materials.

8.3 Pest control measures shall be implemented to prevent infestation of the warehouse.

8.4 Waste materials shall be disposed of properly according to environmental regulations.

8.5 The Environmental Monitoring System (EMS) will be used to continuously monitor and record temperature and humidity.

9.0 TRAINING

9.1 All personnel involved in inventory management and stock control shall be trained on this SOP.

9.2 Training shall be documented, and records shall be maintained.

9.3 Retraining shall be conducted periodically, or whenever there are changes to this SOP.

10.0 DEVIATIONS

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

10.2 The deviation report shall include the date, time, description of the deviation, and the corrective action taken.

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

11.0 REVISION HISTORY

Version No. | Effective Date | Author | Reason for Revision

------- | -------- | -------- | --------

1.0 | 2025-01-01 | | Initial Release

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Materials Management

Title: Inventory Management and Stock Control (FIFO/FEFO)

SOP No.: SOP-WH-006

Version No.: 1.0

Effective Date: 2025-01-01

1.0 PURPOSE

1.1 The purpose of this Standard Operating Procedure (SOP) is to define the procedures for managing inventory and controlling stock levels of all raw materials, packaging materials, and other materials stored within the NovaThera Pharmaceuticals Pvt. Ltd. warehouse, ensuring compliance with Good Manufacturing Practices (GMP) and regulatory requirements. This SOP outlines procedures for receiving, storing, issuing, and tracking materials, emphasizing First-In, First-Out (FIFO) and First-Expired, First-Out (FEFO) principles to maintain material quality and prevent obsolescence.

2.0 SCOPE

2.1 This SOP applies to all personnel involved in the receipt, storage, issuance, and control of materials within the Materials Management department of NovaThera Pharmaceuticals Pvt. Ltd., including

Warehouse Operators, QC Inspectors, Production Supervisors, and other authorized personnel. This SOP covers all materials stored in the warehouse, including raw materials, packaging materials, labels, printed materials, and any other materials used in the manufacturing process.

3.0 RESPONSIBILITIES

3.1 Warehouse Operator: Responsible for the physical receipt, storage, issuance, and movement of materials within the warehouse, adhering to FIFO/FEFO principles and recording all transactions accurately. Responsible for maintaining the cleanliness and organization of the warehouse. Operates equipment such as forklifts (FLK-01), stackers (STK-01), and pallet jacks (PLJ-02) safely and according to SOPs.

3.2 QC Inspector: Responsible for inspecting incoming materials for quality and compliance with specifications, sampling materials for testing, and releasing or rejecting materials based on QC results.

3.3 Production Supervisor: Responsible for requesting materials from the warehouse for production, ensuring that the correct materials are requested and used, and returning any unused materials to the warehouse with proper documentation.

3.4 QA Manager: Responsible for reviewing and approving this SOP, ensuring compliance with GMP and regulatory requirements, and conducting audits to verify adherence to this SOP. Responsible for investigating any deviations from this SOP and implementing corrective and preventive actions (CAPA).

3.5 Head of QA: Responsible for the overall quality assurance system and ensuring that all SOPs are compliant with GMP and regulatory requirements.

4.0 DEFINITIONS

4.1 FIFO (First-In, First-Out): A method of inventory management in which the oldest stock is used first.

4.2 FEFO (First-Expired, First-Out): A method of inventory management in which the stock with the earliest expiration date is used first.

4.3 Material Stock Register: A record used to track the quantity, location, and status of all materials stored in the warehouse.

4.4 Quarantine: The status of materials that are awaiting QC inspection and release.

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

4.6 Rejected: The status of materials that do not meet quality standards and cannot be used in production.

4.7 Batch Number: A unique identifier assigned to a specific quantity of material produced in a single manufacturing run.

4.8 Expiration Date: The date after which a material is no longer considered suitable for use.

4.9 Certificate of Analysis (COA): A document that provides the results of testing performed on a material.

4.10 Deviation: Any departure from approved procedures or specifications.

4.11 CAPA: Corrective and Preventive Action, a systematic process for identifying and eliminating the root causes of deviations and preventing their recurrence.

4.12 Material Safety Data Sheet (MSDS): Now referred to as Safety Data Sheet (SDS), a document that provides information on the potential hazards of a material and how to handle it safely.

4.13 Environmental Monitoring System (EMS): A system used to monitor and control environmental conditions within the warehouse, such as temperature and humidity.

4.14 Line Clearance: The process of removing all materials from a production line before starting a new production run.

4.15 Dispensing Booth: A controlled environment used for weighing and dispensing materials for production.

4.16 WMS: Warehouse Management System

4.17 HVAC: Heating, Ventilation, and Air Conditioning system.

4.18 RFI: Radio Frequency Identification. A technology used for tracking and identifying materials wirelessly.

5.0 PROCEDURE

5.1 Receiving Materials

5.1.1 Upon arrival of materials at the warehouse receiving area, the Warehouse Operator shall verify the delivery against the purchase order (PO) and packing list.

5.1.2 The Warehouse Operator shall visually inspect the materials for any damage or discrepancies. Any damage or discrepancies shall be documented on the receiving report.

5.1.3 The Warehouse Operator shall record the date of receipt, material name, supplier, batch number, quantity, and any other relevant information in the Material Stock Register (either physical or WMS).

5.1.4 The Warehouse Operator shall assign a unique identification number to each received item and attach a corresponding label. Where applicable, an RFI tag can be used in addition to the label for electronic tracking.

5.1.5 The materials shall be moved to the quarantine area and clearly labeled as "QUARANTINED." Equipment used may include pallet jacks (PLJ-02).

5.1.6 The Warehouse Operator shall notify the QC Inspector to sample the materials for testing. The notification will be logged in the WMS.

5.2 QC Inspection and Release

5.2.1 The QC Inspector shall sample the quarantined materials according to the approved sampling plan (document number SMP-001).

5.2.2 The QC Inspector shall perform the required tests on the samples and record the results in the QC testing record (document number QCR-001).

5.2.3 If the materials meet the required specifications, the QC Inspector shall release the materials and update the Material Stock Register (or WMS) accordingly.

5.2.4 If the materials do not meet the required specifications, the QC Inspector shall reject the materials and notify the QA Manager.

5.2.5 Rejected materials shall be clearly labeled as "REJECTED" and moved to the designated rejected materials area. The area will be clearly demarcated and access controlled.

5.3 Storage of Materials

5.3.1 Released materials shall be stored in the designated storage locations according to the material storage map (document number MSM-001) and recorded in the WMS.

5.3.2 Materials shall be stored in a manner that prevents damage or contamination. Storage areas shall be clearly marked with the material name, batch number, and other relevant information.

5.3.3 Temperature and humidity in the storage areas shall be monitored and recorded daily, using calibrated temperature and humidity monitoring devices (THM-01, THM-02). Records shall be reviewed by the Head of QA weekly. Excursions outside of the specified ranges (e.g., 20-25°C and 40-60% RH) must be immediately reported to the QA Manager and investigated. The EMS system will automatically alert relevant personnel if temperature and humidity are outside the acceptable range.

5.3.4 FIFO/FEFO principles shall be strictly followed when storing materials. The Warehouse Operator, utilizing equipment such as forklifts (FLK-01) and stackers (STK-01), shall ensure that older materials are stored in front of newer materials and that materials with earlier expiry dates are easily accessible. The WMS system will guide the Warehouse Operator to the correct storage location based on FIFO/FEFO requirements.

5.3.5 Hazardous materials shall be stored in designated areas with appropriate safety precautions, adhering to SDS guidelines. These areas will be clearly marked with hazard symbols and safety information.

5.3.6 The warehouse layout is detailed in document LAY-001 and the storage location of materials is recorded in the WMS. The WMS will be used to optimize storage locations based on material type, size, and frequency of use.

5.3.7 Periodically (at least annually), the material storage map will be reviewed and updated by the Materials Management department, ensuring that storage locations are appropriate and efficient.

5.4 Issuance of Materials

5.4.1 Production Supervisor shall submit a material request form to the warehouse, specifying the materials required, quantity, batch number, and production order number. The material request form will be submitted

electronically through the WMS.

5.4.2 The Warehouse Operator shall verify the material request form against the production schedule. The WMS will automatically verify the material request against the production schedule and available inventory.

5.4.3 The Warehouse Operator shall select the materials for issuance according to FIFO/FEFO principles, ensuring that the materials with the earliest expiration dates are issued first. The WMS will guide the Warehouse Operator to select the correct materials based on FIFO/FEFO requirements.

5.4.4 The Warehouse Operator shall record the issuance of materials in the Material Stock Register (or WMS), including the date, quantity, batch number, and production order number. The WMS will automatically record the issuance of materials.

5.4.5 The materials shall be transferred to the production area, along with the corresponding COA (if applicable). The transfer will be documented in the WMS.

5.5 Return of Unused Materials

5.5.1 Any unused materials remaining after production shall be returned to the warehouse with a return material form (document number RMF-001).

5.5.2 The Warehouse Operator shall verify the returned materials against the return material form and inspect the materials for any damage or contamination.

5.5.3 If the materials are in good condition, the Warehouse Operator shall return them to the designated storage locations and update the Material Stock Register (or WMS) accordingly.

5.5.4 If the materials are damaged or contaminated, the Warehouse Operator shall notify the QC Inspector for evaluation. The returned materials will be placed in a designated quarantine area pending QC evaluation.

5.6 Inventory Reconciliation

5.6.1 A physical inventory count shall be conducted on a periodic basis (e.g., monthly, quarterly, annually) to reconcile the physical inventory with the Material Stock Register (or WMS) records.

5.6.2 Any discrepancies between the physical inventory and the Material Stock Register (or WMS) records shall be investigated and resolved.

5.6.3 The results of the inventory reconciliation shall be documented and reviewed by the QA Manager.

5.6.4 Cycle counts will be conducted on a weekly basis for high-value items. The WMS will be used to generate cycle count schedules and track the progress of cycle counts.

5.6.5 Reconciliation activities will be documented in reconciliation report (document number REC-001).

5.7 Flow of Materials

5.7.1 The flow of materials within the warehouse shall be unidirectional, from the receiving area to the quarantine area, then to the released storage area, and finally to the issuance area.

5.7.2 The flow of materials shall be designed to minimize the risk of cross-contamination and ensure proper segregation of materials.

5.7.3 Material movement will be tracked using the WMS and physical logs. The WMS will provide real-time visibility into the location and status of all materials within the warehouse.

5.8 Reconciliation of Raw and Packing Materials

5.8.1 Raw and packing materials issued to production are reconciled after each batch. This includes reconciliation of labels, printed materials and other packing materials.

5.8.2 A reconciliation report is prepared by the Production Supervisor and reviewed by the QA Manager. The reconciliation report (document number RPR-001) will include details of materials issued, materials used, and materials returned.

5.8.3 Discrepancies are investigated, and corrective actions implemented. All discrepancies and corrective actions will be documented in a deviation report.

5.9 Entry in Material Stock Register

5.9.1 All material movements (receipt, release, issuance, return, adjustments) are recorded in the Material Stock Register (or WMS) immediately.

5.9.2 Entries include date, material name, batch number, quantity, supplier, QC status, and any relevant comments.

5.9.3 The Material Stock Register (or WMS) is reviewed periodically by the Head of QA to ensure accuracy and completeness. The WMS will generate reports to facilitate this review.

5.9.4 All entries will be made electronically and will be auditable.

5.10 Physical Verification Handling of Excess and Shortages of Materials

5.10.1 Excess materials found during physical verification are investigated to determine the cause. The excess materials are properly labeled, recorded, and stored. The Material Stock Register (or WMS) is updated.

5.10.2 Shortages of materials found during physical verification are investigated to determine the cause. The shortage is documented, and corrective actions are implemented. The Material Stock Register (or WMS) is updated.

5.10.3 Any adjustments to the Material Stock Register (or WMS) are approved by the QA Manager.

5.10.4 A root cause analysis will be conducted for any significant discrepancies (defined as exceeding 5% of the expected quantity or any discrepancy for controlled substances).

5.11 Line Clearance Procedure

5.11.1 Before the start of a new production run, a thorough line clearance shall be performed to ensure that all materials from the previous production run have been removed.

5.11.2 The Production Supervisor shall inspect the production line and verify that it is free of any materials, documents, or equipment from the previous production run.

5.11.3 The line clearance shall be documented and signed off by the Production Supervisor.

5.11.4 The line clearance checklist (LCL-001) must be completed before the start of each production run.

5.11.5 The line clearance will include a visual inspection of the area, as well as verification against the Bill of Materials for the previous batch.

5.12 Dispensing Booth Operations

5.12.1 Materials are dispensed in a controlled dispensing booth to ensure accuracy and prevent contamination.

5.12.2 The dispensing booth is cleaned and sanitized before and after each use according to SOP-CL-005. A logbook will be maintained to record cleaning and sanitization activities.

5.12.3 The weighing equipment (e.g., TCP-01) is calibrated regularly according to a calibration schedule. Calibration records will be maintained.

5.12.4 Only authorized personnel are allowed to operate the dispensing booth. A list of authorized personnel will be maintained and reviewed periodically.

5.12.5 The dispensing booth will be equipped with a HEPA filter to remove airborne particles. The HEPA filter will be tested regularly to ensure its effectiveness.

5.13 Temperature and Humidity Monitoring

5.13.1 Temperature and humidity in the warehouse are monitored continuously using calibrated temperature and humidity monitoring devices (THM-01, THM-02).

5.13.2 The temperature and humidity readings are recorded at least twice daily. The EMS system automatically records temperature and humidity continuously.

5.13.3 If the temperature or humidity exceeds the specified limits, corrective actions are taken immediately, such as adjusting the HVAC system or using dehumidifiers. An investigation will be conducted to determine the cause of the excursion.

5.13.4 The temperature and humidity records are reviewed by the Head of QA weekly.

5.13.5 The calibration of the temperature and humidity monitoring devices will be performed annually or more frequently if required.

5.14 Cleaning and Maintenance

5.14.1 The warehouse is cleaned regularly according to a documented cleaning schedule (CLS-001).

5.14.2 Cleaning materials are appropriate for pharmaceutical use and do not contaminate the materials stored in the warehouse. A list of approved cleaning materials will be maintained.

5.14.3 Cleaning records are maintained.

5.14.4 Equipment such as forklifts (FLK-01), stackers (STK-01), and pallet jacks (PLJ-02) are maintained according to a preventative maintenance schedule (PMS-001). Maintenance records will be maintained.

6.0 DOCUMENTATION

6.1 The following documents shall be maintained:

- Purchase Orders
- Packing Lists
- Receiving Reports
- Material Stock Register (or WMS records)
- QC Testing Records
- Certificates of Analysis (COAs)
- Material Request Forms
- Return Material Forms
- Inventory Reconciliation Reports
- Temperature and Humidity Records
- Cleaning Records

- Equipment Maintenance Records
- Deviation Reports
- CAPA Reports
- Line Clearance Checklists
- Calibration Records
- Training Records
- Sampling Plan (SMP-001)
- QC Testing Record (QCR-001)
- Material Storage Map (MSM-001)
- Warehouse Layout (LAY-001)
- Return Material Form (RMF-001)
- Reconciliation Report (REC-001)
- Reconciliation Report (RPR-001)
- Cleaning Schedule (CLS-001)
- Preventative Maintenance Schedule (PMS-001)

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

6.3 All documents shall be retained for the period specified in the document retention policy. Electronic records will be backed up regularly.

7.0 SAFETY PRECAUTIONS

7.1 All personnel shall follow safety procedures when handling materials, including wearing appropriate personal protective equipment (PPE) such as safety glasses, gloves, and safety shoes.

7.2 Hazardous materials shall be handled according to the SDS. Personnel handling hazardous materials will receive specific training.

7.3 Equipment such as forklifts (FLK-01), stackers (STK-01), and pallet jacks (PLJ-02) shall be operated safely and according to the manufacturer's instructions and relevant SOPs. Only trained and authorized personnel are permitted to operate this equipment. Regular safety inspections of the equipment will be performed.

7.4 Fire safety equipment shall be readily available and maintained in good working order. Fire drills will be conducted regularly.

7.5 Emergency procedures shall be established and communicated to all personnel. Emergency contact information will be prominently displayed.

8.0 ENVIRONMENTAL CONTROLS

8.1 The warehouse shall be maintained in a clean and orderly condition to prevent contamination of materials.

8.2 Temperature and humidity shall be controlled to ensure the stability of materials.

8.3 Pest control measures shall be implemented to prevent infestation of the warehouse. A pest control logbook will be maintained.

8.4 Waste materials shall be disposed of properly according to environmental regulations. Waste disposal records will be maintained.

8.5 The Environmental Monitoring System (EMS) will be used to continuously monitor and record temperature and humidity.

8.6 Air filtration systems will be used to maintain air quality within the warehouse. Air filters will be replaced regularly.

9.0 TRAINING

9.1 All personnel involved in inventory management and stock control shall be trained on this SOP.

9.2 Training shall be documented, and records shall be maintained.

9.3 Retraining shall be conducted periodically, or whenever there are changes to this SOP.

9.4 Training will include practical exercises and assessments to ensure competency.

10.0 DEVIATIONS

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

10.2 The deviation report shall include the date, time, description of the deviation, and the corrective action taken.

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

10.4 A root cause analysis will be performed for all significant deviations.

11.0 REVISION HISTORY

Version No. | Effective Date | Author | Reason for Revision

------- | -------- | -------- | --------

1.0 | 2025-01-01 | | Initial Release

Document Approval

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

Document Control Information

Document ID: SOP-WH-006

Version: 1.0

Effective Date: 2025-01-01

Next Review Date: 2026-01-01

Generated by: NovaThera SOP Generator System