Document Type:	Standard Operating Procedure (SOP)	**SOP Code:**	SOP-WH-002
Title:	Storage and Handling of Quarantined Materials	**Version:**	1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
Location:	Pune, India	**Review Date:**	2026-01-01

Storage and Handling of Quarantined Materials

Category: Materials Management

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Materials Management

Title: Storage and Handling of Quarantined Materials

SOP No.: SOP-WH-002

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 the storage and handling of quarantined materials (Raw Material & Packing Materials), Re-test Materials, rejected materials and physical verification handling of excess and shortages of materials at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India.

2.0 SCOPE

2.1 This SOP applies to all personnel involved in the receipt, storage, handling, and dispensing of quarantined materials within the Materials Management Department at NovaThera Pharmaceuticals Pvt. Ltd., Pune. This includes the Warehouse Operator, QC Inspector, Production Supervisor, QA Manager, and any other personnel authorized to handle quarantined materials.

3.0 RESPONSIBILITIES

3.1 Warehouse Operator: Responsible for the physical handling, storage, and movement of quarantined materials according to this SOP. They are also responsible for maintaining accurate inventory records and promptly reporting any discrepancies to the Production Supervisor and QA Manager.

3.2 QC Inspector: Responsible for sampling and inspecting quarantined materials, and for releasing or rejecting materials based on QC testing results. They are also responsible for the proper labeling of

materials status (quarantine, approved, rejected).

3.3 Production Supervisor: Responsible for overseeing the proper use of quarantined materials in the production process and ensuring that all activities are performed according to GMP requirements. They are also responsible for investigating any discrepancies related to quarantined materials.

3.4 QA Manager: Responsible for ensuring that this SOP is followed, for approving any deviations from the SOP, and for maintaining the overall quality system related to materials management. The QA Manager is also responsible for the periodic review and approval of this SOP.

3.5 Head of QA: Responsible for the final approval of this SOP and any revisions made to it.

4.0 DEFINITIONS

4.1 Quarantined Materials: Materials that have been received but have not yet been approved for use by Quality Control. These materials are held in a designated quarantine area.

4.2 Approved Materials: Materials that have been sampled, tested, and approved for use by Quality Control.

4.3 Rejected Materials: Materials that have been sampled, tested, and found to be non-conforming by Quality Control.

4.4 Re-test Materials: Materials which are beyond the shelf life after approval and QC Inspector instruct for re-testing.

4.5 FIFO (First-In, First-Out): An inventory management method where the oldest stock is used first.

4.6 FEFO (First-Expired, First-Out): An inventory management method where the stock with the earliest expiration date is used first.

4.7 Deviation: Any unplanned departure from an approved procedure or instruction.

4.8 GMP: Good Manufacturing Practices.

4.9 FDA: Food and Drug Administration.

4.10 ICH: International Council for Harmonisation.

4.11 Material Safety Data Sheet (MSDS): Document that contains information on the potential hazards (health, fire, reactivity and environmental) and how to work safely with the chemical product.

4.12 Equipment Codes: Defined unique codes for each equipment for easy identification and traceability. BLN-04 (Balance), TCP-01 (Temperature Chart Printer), SFT-02 (Forklift), STK-01 (Stacker)

5.0 PROCEDURE

5.1 Receipt and Identification of Quarantined Materials:

5.1.1 Upon receipt of materials, the Warehouse Operator shall verify the following information against the purchase order and delivery documents:

• Material name and code

• Quantity received

• Batch number

• Manufacturer's name

• Date of receipt

• Physical condition of the consignment. Any discrepancies shall be documented and reported to the Production Supervisor and QA Manager immediately.

5.1.2 The Warehouse Operator shall assign a unique internal identification number (e.g., QR-YYYY-MM-DD-XXX, where QR indicates Quarantined Receipt, YYYY-MM-DD is the date, and XXX is a sequential number) to each received material and record it in the Quarantine Material Logbook.

5.1.3 The Warehouse Operator shall affix a "QUARANTINED" label to each container or pallet of the received material, clearly indicating the material name, code, batch number, internal identification number, and date of receipt.

5.2 Storage of Quarantined Materials:

5.2.1 Quarantined materials shall be stored in a designated quarantine area, physically separated from approved and rejected materials. The quarantine area shall be clearly marked with appropriate signage.

5.2.2 The quarantine area shall be maintained at the specified temperature and humidity conditions as per the material storage requirements and documented in the Material Safety Data Sheet (MSDS). Temperature and humidity shall be monitored continuously using calibrated monitoring devices (e.g., TCP-01) and recorded at least twice daily. Any excursions outside the specified limits shall be reported to the Production Supervisor and QA Manager immediately.

5.2.3 Materials shall be stored in a manner that prevents damage, contamination, or mix-up. Pallets shall be used to elevate materials off the

floor. Aisles shall be kept clear for easy access and inspection.

5.2.4 Flammable materials shall be stored in a designated fire-resistant area, in accordance with safety regulations and the MSDS.

5.2.5 The location of each quarantined material shall be recorded in the Quarantine Material Logbook, indicating the storage area, rack number, and shelf number.

5.2.6 The warehouse should make use of STK-01 to move the pallet and arrange the rack numbers.

5.3 Sampling and Inspection:

5.3.1 Upon notification from the QC Inspector, the Warehouse Operator shall retrieve the required quantity of material for sampling, following the instructions provided by QC.

5.3.2 The Warehouse Operator shall transfer the material to the sampling area, ensuring that the integrity of the material is maintained during transportation.

5.3.3 After sampling, the Warehouse Operator shall return the material to its designated quarantine storage location.

5.3.4 The QC Inspector shall perform sampling and inspection according to the relevant sampling plan and test method.

5.3.5 The QC Inspector shall document the sampling and inspection results in the appropriate QC records.

5.4 Release or Rejection of Quarantined Materials:

5.4.1 Based on the QC testing results, the QC Inspector shall determine whether the material is approved or rejected.

5.4.2 If the material is approved, the QC Inspector shall update the status of the material in the Quarantine Material Logbook and affix an "APPROVED" label to each container or pallet. The "QUARANTINED" label shall be removed or clearly marked as superseded.

5.4.3 If the material is rejected, the QC Inspector shall update the status of the material in the Quarantine Material Logbook and affix a "REJECTED" label to each container or pallet. The "QUARANTINED" label shall be removed or clearly marked as superseded. A rejection report shall be initiated detailing the reasons for rejection.

5.4.4 The QA Manager shall review and approve the QC Inspector's decision and authorize the movement of the material to the appropriate storage location (approved or rejected area).

5.5 Storage of Approved Materials:

5.5.1 Approved materials shall be transferred to a designated approved storage area, physically separated from quarantined and rejected materials. The approved area shall be clearly marked with appropriate signage.

5.5.2 Approved materials shall be stored in a manner that prevents damage, contamination, or mix-up, following the same storage conditions as outlined in Section 5.2.

5.5.3 The location of each approved material shall be recorded in the Approved Material Logbook, indicating the storage area, rack number, and shelf number.

5.5.4 FIFO/FEFO inventory management principles shall be followed. The Warehouse Operator shall ensure that materials with the earliest expiration dates are used first.

5.6 Storage and Handling of Rejected Materials:

5.6.1 Rejected materials shall be transferred to a designated rejected storage area, physically separated from quarantined and approved materials. The rejected area shall be clearly marked with appropriate signage.

5.6.2 Rejected materials shall be stored in a manner that prevents unauthorized use or accidental mixing with approved materials.

5.6.3 The location of each rejected material shall be recorded in the Rejected Material Logbook, indicating the storage area, rack number, and shelf number.

5.6.4 A destruction plan for the rejected material must be in place, approved by the QA Manager, and executed within a specified timeframe. All destruction activities must be documented.

5.6.5 If the rejected material is to be returned to the supplier, the QA Manager shall ensure that the necessary documentation is prepared and that the return shipment is handled according to applicable regulations.

5.7 Handling of Re-test Materials:

5.7.1 After the QC Inspector instructed to test the re-test material, the Warehouse Operator shall retrieve the required quantity of material for sampling, following the instructions provided by QC.

5.7.2 The Warehouse Operator shall transfer the material to the sampling area, ensuring that the integrity of the material is maintained during transportation.

5.7.3 The QC Inspector shall perform sampling and inspection according to the relevant sampling plan and test method.

5.7.4 If the material is approved, the QC Inspector shall update the status of the material in the Approved Material Logbook and affix an "APPROVED" label to each container or pallet.

5.7.5 If the material is rejected, the QC Inspector shall update the status of the material in the Rejected Material Logbook and affix a "REJECTED" label to each container or pallet. A rejection report shall be initiated detailing the reasons for rejection.

5.8 Dispensing of Approved Materials:

5.8.1 Upon receipt of a material request from the Production Supervisor, the Warehouse Operator shall retrieve the required quantity of material from the approved storage area.

5.8.2 The Warehouse Operator shall verify the material name, code, batch number, and quantity against the material request.

5.8.3 The Warehouse Operator shall dispense the material in a designated dispensing area, using calibrated weighing equipment (e.g., BLN-04).

5.8.4 The dispensing area shall be cleaned and inspected before and after each dispensing operation, following the cleaning procedure outlined in Section 5.10.

5.8.5 The Warehouse Operator shall document the dispensing activity in the Material Dispensing Logbook, recording the material name, code, batch number, quantity dispensed, date of dispensing, and the name of the Production Supervisor who requested the material.

5.8.6 The dispensed material shall be transferred to the production area in a closed container, labeled with the material name, code, batch number, and quantity.

5.9 Physical Verification Handling of Excess and Shortages of Materials:

5.9.1 Physical inventory counts shall be conducted periodically (e.g., monthly, quarterly, annually) to verify the accuracy of inventory records.

5.9.2 Any discrepancies between the physical count and the inventory records shall be investigated by the Production Supervisor and the QA Manager.

5.9.3 If excess material is found, the Warehouse Operator shall record the excess in the Material Inventory Adjustment Logbook and store the material in the appropriate storage area (quarantined, approved, or rejected), depending on its status. The reason for the excess must be investigated.

5.9.4 If a shortage of material is found, the Warehouse Operator shall record the shortage in the Material Inventory Adjustment Logbook and initiate an investigation to determine the cause of the shortage. Corrective and preventive actions (CAPA) shall be implemented to prevent future shortages.

5.10 Cleaning and Maintenance:

5.10.1 The storage areas (quarantine, approved, and rejected) shall be cleaned regularly, following a documented cleaning schedule.

5.10.2 The cleaning procedure shall include the removal of dust, debris, and any spilled materials.

5.10.3 Cleaning agents shall be appropriate for the materials being stored and shall not leave any residue that could contaminate the materials.

5.10.4 Cleaning activities shall be documented in the Cleaning Logbook, indicating the date, time, area cleaned, cleaning agent used, and the name of the person performing the cleaning.

5.10.5 Equipment used for handling materials (e.g., forklifts SFT-02, pallet jacks) shall be maintained in good working order and inspected regularly. Maintenance activities shall be documented in the Equipment Maintenance Logbook.

5.11 Temperature and Humidity Monitoring:

5.11.1 Temperature and humidity in the storage areas shall be monitored continuously using calibrated monitoring devices (e.g., TCP-01).

5.11.2 Temperature and humidity readings shall be recorded at least twice daily in the Temperature and Humidity Monitoring Logbook.

5.11.3 Any excursions outside the specified limits shall be reported to the Production Supervisor and QA Manager immediately.

5.11.4 Corrective actions shall be taken to bring the temperature and humidity back within the specified limits, and the corrective actions shall be documented in the Temperature and Humidity Monitoring Logbook.

5.12 Line Clearance:

5.12.1 Before and after any dispensing activity, a line clearance shall be performed in the dispensing area to ensure that all materials from the previous dispensing activity have been removed.

5.12.2 The line clearance shall include a visual inspection of the dispensing area, including the weighing equipment, work surfaces, and surrounding areas.

5.12.3 The line clearance shall be documented in the Line Clearance Logbook, indicating the date, time, area cleared, and the name of the person performing the line clearance.

5.13 Dispensing Booth Operations:

5.13.1 Dispensing shall be performed in a dedicated dispensing booth to minimize the risk of contamination.

5.13.2 The dispensing booth shall be equipped with appropriate ventilation and air filtration systems.

5.13.3 The dispensing booth shall be cleaned and disinfected before and after each dispensing operation.

6.0 SAFETY PRECAUTIONS

6.1 All personnel handling materials shall wear appropriate personal protective equipment (PPE), including safety glasses, gloves, and respiratory protection, as required by the MSDS.

6.2 Materials shall be handled in a manner that prevents spills, leaks, or damage.

6.3 Flammable materials shall be handled with extra caution and stored in designated fire-resistant areas.

6.4 Personnel shall be trained on the proper handling of hazardous materials and on the procedures for responding to spills or leaks.

6.5 Emergency contact information and spill response procedures shall be posted in a conspicuous location.

6.6 Ensure SFT-02 is operated by trained personnel only.

7.0 DOCUMENTATION

7.1 The following documents shall be maintained:

- Quarantine Material Logbook
- Approved Material Logbook
- Rejected Material Logbook
- Material Dispensing Logbook
- Material Inventory Adjustment Logbook
- Cleaning Logbook
- Equipment Maintenance Logbook
- Temperature and Humidity Monitoring Logbook

- Line Clearance Logbook
- Purchase Orders
- Delivery Documents
- QC Test Results
- Rejection Reports
- Training Records

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

7.3 All records shall be retained for a period of [Specify Retention Period] as per the document retention policy.

7.4 Electronic records shall be backed up regularly to prevent data loss.

8.0 DEVIATIONS

8.1 Any deviation from this SOP shall be documented in a deviation report, including the date, time, nature of the deviation, and the reason for the deviation.

8.2 The deviation report shall be reviewed and approved by the Production Supervisor and the QA Manager.

8.3 Corrective and preventive actions (CAPA) shall be implemented to prevent future deviations.

9.0 TRAINING

9.1 All personnel involved in the storage and handling of quarantined materials shall be trained on this SOP.

9.2 Training shall include a review of the SOP, a demonstration of the procedures, and a practical assessment.

9.3 Training records shall be maintained for all personnel.

10.0 REVISION HISTORY

Version No. | Effective Date | Changes Made | Reason for Change | Prepared By | Approved By

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

1.0 | 2025-01-01 | Initial Release| New SOP | | Head of QA

Document Approval

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

Document Control Information

Document ID: SOP-WH-002

Version: 1.0

Effective Date: 2025-01-01

Next Review Date: 2026-01-01

Generated by: NovaThera SOP Generator System