Document Type:	Standard Operating Procedure (SOP)	**SOP Code:**	SOP-WH-004
Title:	Storage and Handling of Rejected 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 Rejected Materials

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 procedures for the identification, segregation, storage, handling, and disposal of rejected raw materials, rejected packing materials, non-moving materials, and expired materials at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India. This SOP ensures compliance with Good Manufacturing Practices (GMP) and relevant regulatory guidelines, minimizing the risk of contamination, mix-ups, and unauthorized use of non-conforming materials.

2.0 SCOPE

This SOP applies to all personnel involved in the receipt, sampling, storage, handling, quality control, and disposal of raw materials, packing materials, in-process materials, and finished goods within the Materials Management department, Quality Control department, and Production department at NovaThera Pharmaceuticals Pvt. Ltd. This includes, but is not limited to, rejected materials, non-moving materials, and expired materials.

3.0 RESPONSIBILITIES

3.1 Warehouse Operator:

- Responsible for the physical segregation and movement of rejected, non-moving, and expired materials.

• Responsible for proper labeling and documentation of rejected, non-moving, and expired materials.

• Responsible for maintaining the designated storage areas in a clean and organized manner.

• Responsible for adhering to FIFO/FEFO principles when handling materials.

• Responsible for operating material handling equipment (e.g., BLN-04, TCP-01, SFT-02, STK-01) safely and efficiently.

• Responsible for monitoring and recording temperature and humidity in storage areas.

3.2 QC Inspector:

• Responsible for the initial inspection and identification of rejected materials.

• Responsible for documenting the reason for rejection on the appropriate forms.

• Responsible for assigning a "Rejected" status in the ERP system.

• Responsible for ensuring proper sampling and testing of rejected materials, if required.

• Responsible for reviewing documentation related to rejected materials.

3.3 Production Supervisor:

• Responsible for identifying and reporting rejected in-process materials.

• Responsible for ensuring that rejected in-process materials are properly segregated and labeled.

• Responsible for initiating investigations into the root cause of material rejections.

3.4 QA Manager:

• Responsible for overseeing the overall management of rejected, non-moving, and expired materials.

• Responsible for reviewing and approving investigations related to material rejections.

• Responsible for making final decisions regarding the disposition of rejected, non-moving, and expired materials.

• Responsible for ensuring compliance with GMP and regulatory requirements.

• Responsible for approving destruction procedures for rejected and expired materials.

• Responsible for reviewing and approving this SOP.

3.5 Head of QA:

• Final approval of destruction records, and the SOP.

4.0 DEFINITIONS

4.1 Rejected Material: Any raw material, packing material, or finished product that does not meet the pre-defined quality standards or specifications.

4.2 Non-Moving Material: Any raw material, packing material, or finished product that has not been issued or used within a defined period (e.g., 12 months).

4.3 Expired Material: Any raw material, packing material, or finished product that has passed its expiration date.

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

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

4.6 ERP: Enterprise Resource Planning, a system used for managing and integrating business processes.

4.7 Quarantine Area: A designated area for holding materials that are awaiting quality control inspection or disposition.

4.8 Rejected Area: A designated area for holding materials that have been rejected by quality control.

4.9 Non-Moving Material Area: A designated area for holding materials that are identified as non-moving.

4.10 Destruction Area: A designated area for materials awaiting destruction.

4.11 BLN-04: Battery Operated Pallet Truck.

4.12 TCP-01: Electric Forklift.

4.13 SFT-02: Manual Stacker.

4.14 STK-01: Reach Truck.

5.0 PROCEDURE

5.1 Handling of Rejected Raw Materials and Packing Materials:

5.1.1 Identification and Segregation:

• Upon receipt of raw materials or packing materials, the Warehouse Operator will visually inspect the materials for any damage or discrepancies.

• If any damage or discrepancies are identified, the Warehouse Operator will immediately notify the QC Inspector.

• The QC Inspector will perform a detailed inspection of the materials and determine if they meet the pre-defined quality standards.

• If the materials do not meet the quality standards, the QC Inspector will assign a "Rejected" status to the materials in the ERP system and generate a rejection notification.

• The QC Inspector will clearly mark the rejected materials with a "REJECTED" label, including the date of rejection, the reason for rejection, the material code, and the batch number.

• The Warehouse Operator will immediately move the rejected materials to the designated "Rejected Area" using appropriate material handling equipment (e.g., BLN-04, TCP-01).

• The "Rejected Area" must be clearly demarcated and physically separated from the "Quarantine Area" and the "Approved Area."

• Access to the "Rejected Area" will be restricted to authorized personnel only.

5.1.2 Documentation:

• The QC Inspector will complete a "Material Rejection Report" detailing the reason for rejection, the quantity rejected, the material code, the batch number, and any other relevant information.

• The "Material Rejection Report" will be reviewed and approved by the QA Manager.

• All documentation related to the rejected materials will be maintained in a designated file.

• The ERP system will be updated to reflect the "Rejected" status of the materials.

5.1.3 Investigation:

• The Production Supervisor, in conjunction with the QC Inspector, will initiate an investigation to determine the root cause of the material rejection.

• The investigation will include a review of the supplier's Certificate of Analysis (COA), the material specifications, and the sampling and testing procedures.

• The investigation findings will be documented in a "Material Rejection Investigation Report."

• The "Material Rejection Investigation Report" will be reviewed and approved by the QA Manager.

5.1.4 Disposition:

• Based on the investigation findings, the QA Manager will determine the appropriate disposition of the rejected materials.

• Possible dispositions include:

• Return to Supplier: The rejected materials may be returned to the supplier for replacement or credit.

• Reworking: If possible, the rejected materials may be reworked to meet the quality standards.

• Destruction: If the rejected materials cannot be returned or reworked, they will be destroyed in accordance with the "Destruction of Rejected Materials" procedure (Section 5.4).

• The disposition decision will be documented in the "Material Rejection Report" and approved by the QA Manager.

5.2 Handling of Non-Moving Raw Materials, Packing Materials, and Finished Products:

5.2.1 Identification and Segregation:

• The Warehouse Operator will conduct a periodic review of the inventory to identify any raw materials, packing materials, or finished products that have not been issued or used within a defined period (e.g., 12 months).

• The Warehouse Operator will notify the QC Inspector of any materials identified as non-moving.

• The QC Inspector will assess the quality and suitability of the non-moving materials for future use.

• The QC Inspector will consider factors such as the expiration date, storage conditions, and the likelihood of degradation.

• If the QC Inspector determines that the non-moving materials are still suitable for use, they will update the "Date of Review" in the ERP System and maintain the materials in their current storage location. Ensure FIFO/FEFO is followed.

• If the QC Inspector determines that the non-moving materials are no longer suitable for use, they will assign a "Rejected" status to the materials in the ERP system and generate a rejection notification.

• The QC Inspector will clearly mark the rejected non-moving materials with a "REJECTED" label, including the date of rejection, the reason for rejection (e.g., "Non-Moving"), the material code, and the batch number.

• The Warehouse Operator will move the rejected non-moving materials to the designated "Non-Moving Material Area" using appropriate material handling equipment (e.g., SFT-02, STK-01).

• The "Non-Moving Material Area" must be clearly demarcated and physically separated from the "Quarantine Area" and the "Approved Area."

• Access to the "Non-Moving Material Area" will be restricted to authorized personnel only.

5.2.2 Documentation:

• The QC Inspector will complete a "Non-Moving Material Assessment Report" detailing the reason for the assessment, the quantity of non-moving material, the material code, the batch number, and the QC Inspector's recommendation.

• The "Non-Moving Material Assessment Report" will be reviewed and approved by the QA Manager.

• All documentation related to the non-moving materials will be maintained in a designated file.

• The ERP system will be updated to reflect the "Rejected" status of the materials, if applicable.

5.2.3 Disposition:

• Based on the QC Inspector's assessment and the QA Manager's review, a disposition decision will be made regarding the non-moving materials.

• Possible dispositions include:

• Re-Evaluation: The non-moving materials may be re-evaluated for suitability for use in a specific product or process.

• Return to Supplier: If the materials are still within their expiration date and meet the quality standards, they may be returned to the supplier for credit or exchange.

• Destruction: If the non-moving materials are no longer suitable for use or cannot be returned, they will be destroyed in accordance with the "Destruction of Rejected Materials" procedure (Section 5.4).

• The disposition decision will be documented in the "Non-Moving Material Assessment Report" and approved by the QA Manager.

5.3 Handling of Expired Raw Materials, Packing Materials, and Finished Products:

5.3.1 Identification and Segregation:

• The Warehouse Operator will monitor the expiration dates of all raw materials, packing materials, and finished products.

• Prior to the expiration date, the Warehouse Operator will notify the QC Inspector of any materials that are approaching their expiration date.

• Upon expiration, the QC Inspector will assign a "Rejected" status to the expired materials in the ERP system and generate a rejection notification.

• The QC Inspector will clearly mark the expired materials with an "EXPIRED" label, including the date of expiration, the material code, and the batch number.

• The Warehouse Operator will immediately move the expired materials to the designated "Expired Material Area" using appropriate material handling equipment (e.g., BLN-04, TCP-01, SFT-02, STK-01).

• The "Expired Material Area" must be clearly demarcated and physically separated from the "Quarantine Area" and the "Approved Area."

• Access to the "Expired Material Area" will be restricted to authorized personnel only.

5.3.2 Documentation:

• The QC Inspector will complete an "Expired Material Report" detailing the material code, the batch number, the quantity expired, and the expiration date.

• The "Expired Material Report" will be reviewed and approved by the QA Manager.

• All documentation related to the expired materials will be maintained in a designated file.

• The ERP system will be updated to reflect the "Rejected" status of the materials.

5.3.3 Disposition:

• Expired materials will be destroyed in accordance with the "Destruction of Rejected Materials" procedure (Section 5.4).

• No expired materials will be used in the manufacturing process or released for sale.

• The destruction of expired materials will be documented in the "Expired Material Report" and approved by the QA Manager.

5.4 Destruction of Rejected, Expired, and Non-Moving Materials:

5.4.1 Preparation:

• The QA Manager will authorize the destruction of rejected, expired, and non-moving materials by signing the appropriate "Material Rejection Report," "Non-Moving Material Assessment Report," or "Expired Material Report."

• A "Destruction Request Form" will be completed, detailing the materials to be destroyed, the quantity, the material code, the batch number, the reason for destruction, and the proposed method of destruction.

• The "Destruction Request Form" will be approved by the QA Manager and Head of QA.

• The Warehouse Operator will move the materials to be destroyed to the designated "Destruction Area" using appropriate material handling equipment (e.g., TCP-01).

• The "Destruction Area" must be a secure area with restricted access.

5.4.2 Destruction Procedure:

• The destruction procedure will be performed by authorized personnel only, under the supervision of the QA Manager or a designated representative.

• The destruction method will be appropriate for the type of material being destroyed and will comply with all applicable environmental regulations.

• Common destruction methods include:

• Incineration: Materials are burned in an incinerator designed for pharmaceutical waste.

• Chemical Degradation: Materials are chemically treated to render them unusable.

• Landfill Disposal: Materials are disposed of in a licensed landfill. (This is the least favored option and should only be used when other methods are not feasible).

• During the destruction process, care will be taken to prevent contamination of the surrounding environment.

• Appropriate personal protective equipment (PPE), such as gloves, masks, and eye protection, will be worn by all personnel involved in the destruction process.

5.4.3 Documentation:

• A "Destruction Record" will be completed, detailing the date of destruction, the materials destroyed, the quantity, the material code, the batch number, the method of destruction, and the names of the personnel involved.

• The "Destruction Record" will be signed and dated by the personnel who performed the destruction.

• The QA Manager will review the "Destruction Record" to ensure that the destruction was performed in accordance with the approved procedure.

• The QA Manager will sign and date the "Destruction Record" to indicate approval.

• The "Destruction Record" will be maintained in a designated file, along with the "Destruction Request Form" and the relevant "Material Rejection Report," "Non-Moving Material Assessment Report," or "Expired Material Report."

• The ERP system will be updated to reflect the destruction of the materials.

5.4.4 Reconciliation:

- After the destruction is complete, a reconciliation will be performed to ensure that the quantity of materials destroyed matches the quantity authorized for destruction.
- Any discrepancies will be investigated and documented.

6.0 TEMPERATURE AND HUMIDITY MONITORING

6.1 Temperature and humidity monitoring devices (e.g., calibrated data loggers) will be installed in all storage areas where raw materials, packing materials, in-process materials, and finished goods are stored.

6.2 The temperature and humidity will be monitored continuously and recorded at least twice daily.

6.3 The temperature and humidity data will be reviewed regularly to ensure that the storage conditions are within the specified limits.

6.4 If the temperature or humidity exceeds the specified limits, corrective action will be taken immediately to restore the proper storage conditions.

6.5 The temperature and humidity monitoring devices will be calibrated according to a pre-defined schedule.

6.6 Calibration records will be maintained for all temperature and humidity monitoring devices.

7.0 CLEANING AND MAINTENANCE

7.1 All storage areas will be cleaned regularly to prevent the accumulation of dust, dirt, and debris.

7.2 A cleaning schedule will be established and followed.

7.3 Cleaning procedures will be documented.

7.4 Appropriate cleaning agents will be used.

7.5 Material handling equipment (e.g., BLN-04, TCP-01, SFT-02, STK-01) will be maintained in good working order.

7.6 A maintenance schedule will be established and followed.

7.7 Maintenance procedures will be documented.

8.0 DOCUMENTATION AND RECORD KEEPING

8.1 All records related to the storage, handling, and disposal of rejected, non-moving, and expired materials will be maintained in a secure location for a minimum of five years.

8.2 The following records will be maintained:

- Material Rejection Reports
- Material Rejection Investigation Reports
- Non-Moving Material Assessment Reports
- Expired Material Reports
- Destruction Request Forms
- Destruction Records

- Temperature and Humidity Monitoring Records
- Cleaning and Maintenance Records
- Calibration Records

8.3 All records will be accurate, complete, and legible.

8.4 All records will be reviewed and approved by the QA Manager.

9.0 SAFETY PRECAUTIONS

9.1 All personnel involved in the storage, handling, and disposal of rejected, non-moving, and expired materials will be trained on the relevant safety procedures.

9.2 Appropriate personal protective equipment (PPE), such as gloves, masks, and eye protection, will be worn at all times.

9.3 Hazardous materials will be handled with extreme care.

9.4 Emergency procedures will be in place in case of spills or accidents.

9.5 All accidents will be reported immediately.

10.0 ENVIRONMENTAL CONTROLS

10.1 The storage, handling, and disposal of rejected, non-moving, and expired materials will be conducted in a manner that minimizes the impact on the environment.

10.2 Waste materials will be disposed of in accordance with all applicable environmental regulations.

10.3 Measures will be taken to prevent air and water pollution.

10.4 Recycling will be encouraged whenever possible.

11.0 TRAINING

11.1 All personnel involved in the storage, handling, and disposal of rejected, non-moving, and expired materials will be trained on this SOP.

11.2 Training will be provided upon initial assignment and annually thereafter.

11.3 Training records will be maintained.

12.0 SOP REVIEW AND REVISION

12.1 This SOP will be reviewed and revised at least annually, or more frequently if necessary.

12.2 The QA Manager is responsible for initiating and approving revisions to this SOP.

12.3 All revisions will be documented.

13.0 ATTACHMENTS

13.1 Attachment 1: Material Rejection Report Form

13.2 Attachment 2: Non-Moving Material Assessment Report Form

13.3 Attachment 3: Expired Material Report Form

13.4 Attachment 4: Destruction Request Form

13.5 Attachment 5: Destruction Record Form

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-004

Version: 1.0

Effective Date: 2025-01-01

Next Review Date: 2026-01-01

Generated by: NovaThera SOP Generator System