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Title:	Pest Control in the Warehouse	Version:	1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	Effective Date:	2025-01-01
Location:	Pune, India	Review Date:	2026-01-01

Pest Control in the Warehouse

Category: Materials Management

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Materials Management

Title: Pest Control and Cleaning in the Warehouse

SOP No.: SOP-WH-009

Version No.: 1.0

Effective Date: 2025-01-01

1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to define the procedures for pest control, cleaning, entry/exit protocols, and environmental monitoring within the warehouse of NovaThera Pharmaceuticals Pvt. Ltd., Pune, India. This SOP ensures compliance with Good Manufacturing Practices (GMP) and regulatory guidelines, maintaining the quality and integrity of stored materials.

2.0 SCOPE

This SOP applies to all personnel involved in the receipt, storage, handling, dispensing, and dispatch of materials within the warehouse of NovaThera Pharmaceuticals Pvt. Ltd., including raw materials, packaging materials, intermediates, and finished products. This includes Warehouse Operators, QC Inspectors, Production Supervisors, and QA personnel.

3.0 RESPONSIBILITY

3.1 Warehouse Operator: Responsible for performing cleaning and pest control activities as per this SOP. They are also responsible for reporting any deviations or observations to the Production Supervisor.

3.2 Production Supervisor: Responsible for overseeing the implementation of this SOP, ensuring that all warehouse personnel are trained and competent. They are responsible for investigating and addressing any deviations or observations reported by the Warehouse Operator.

3.3 QC Inspector: Responsible for verifying the cleanliness and suitability of the warehouse environment and materials before use. The QC Inspector is responsible for reviewing records and documentation related to pest control and cleaning.

3.4 QA Manager: Responsible for the overall implementation and compliance of this SOP. The QA Manager is responsible for approving revisions to this SOP and ensuring that it is aligned with GMP and regulatory requirements. They also oversee the audit of pest control and cleaning activities.

4.0 DEFINITIONS

4.1 Pest: Any unwanted organism, including insects, rodents, birds, or other animals that can contaminate or damage materials.

4.2 Cleaning: The process of removing dirt, dust, debris, and other contaminants from surfaces.

4.3 Sanitization: The process of reducing the number of microorganisms to a safe level.

4.4 Disinfection: The process of eliminating or inactivating microorganisms on surfaces.

4.5 FIFO: First-In, First-Out; an inventory management principle where the oldest stock is used first.

4.6 FEFO: First-Expiry, First-Out; an inventory management principle where the stock with the earliest expiry date is used first.

4.7 Line Clearance: The process of removing all materials from a production area to prevent mix-ups or cross-contamination.

4.8 Environmental Monitoring: The systematic collection and analysis of data to assess the levels of microorganisms and other contaminants in the environment.

4.9 Stores Area: The defined area within the warehouse used for storing materials.

5.0 PROCEDURE

5.1 Pest Control

5.1.1 Preventive Measures:

• Implement a pest control program in coordination with a licensed pest control service provider.

• Seal all cracks and crevices in the warehouse structure to prevent pest entry.

• Ensure all doors and windows are properly sealed when not in use.

• Install insect screens on windows and doors where necessary.

• Maintain a clean and organized warehouse environment to minimize food sources and harborage for pests.

• Regularly inspect incoming materials for signs of pest infestation. Reject any infested materials.

• Dispose of waste materials promptly and properly in designated, covered containers.

• Maintain vegetation outside the warehouse to prevent pests from entering the building. Cut grass regularly.

• Use air curtains at doorways to prevent insect entry.

• Regularly clean drains to prevent pest breeding.

5.1.2 Pest Monitoring:

• Implement a pest monitoring program using traps (e.g., rodent traps, insect traps) strategically placed throughout the warehouse.

• Regularly inspect traps for signs of pest activity. Maintain a record of trap locations, inspection dates, and any pests captured.

• Use electronic pest monitoring systems to track pest activity in real-time.

• Conduct regular inspections of the warehouse interior and exterior for signs of pest infestation, including droppings, gnaw marks, and nests.

5.1.3 Pest Treatment:

• In the event of pest activity, contact the licensed pest control service provider to implement appropriate treatment measures.

• Use only approved pesticides that are suitable for use in a pharmaceutical warehouse.

• Ensure that all pesticide applications are performed by trained and certified personnel.

• Follow the pest control service provider's recommendations for pesticide application rates and methods.

• Implement integrated pest management (IPM) strategies that minimize the use of pesticides.

• Document all pest control activities, including the date, time, location, pesticide used, and person performing the treatment.

• After pesticide application, thoroughly clean the treated areas to remove any pesticide residue.

5.1.4 Documentation:

• Maintain a pest control logbook to record all pest control activities, including preventive measures, monitoring results, and treatment details.

• Retain all records of pest control service provider visits, inspections, and treatments.

• Document any deviations from the pest control program and the corrective actions taken.

• Review pest control records regularly to assess the effectiveness of the program and identify areas for improvement.

5.2 Cleaning of Stores Area

5.2.1 Frequency:

• Daily cleaning of floors, walls, and storage racks.

• Weekly cleaning of ceilings, light fixtures, and ventilation systems.

• Monthly deep cleaning of the entire warehouse.

5.2.2 Materials and Equipment:

• Use only approved cleaning agents that are suitable for use in a pharmaceutical warehouse. Refer to the approved vendor list.

• Use dedicated cleaning equipment (e.g., mops, buckets, cloths) that are specifically designated for use in the warehouse.

• Ensure that all cleaning equipment is properly cleaned and sanitized after each use.

• Use vacuum cleaners with HEPA filters to minimize the spread of dust and allergens.

• Equipment codes for cleaning equipment include: BLN-04 (Blower), TCP-01 (Trolley Cleaning Platform), SFT-02 (Sweeping Floor Tool).

5.2.3 Procedure:

• Remove all materials from the area to be cleaned.

• Sweep or vacuum the floor to remove loose dirt and debris.

• Wash the floor with an approved cleaning agent and water.

• Rinse the floor with clean water and allow it to dry completely.

• Wipe down walls, storage racks, and other surfaces with an approved cleaning agent.

• Clean light fixtures and ventilation systems with a vacuum cleaner or damp cloth.

• Ensure that all surfaces are dry before returning materials to the area.

• Pay special attention to cleaning spills promptly to prevent contamination.

• Follow manufacturer's instructions for the use of cleaning agents.

• Ensure proper ventilation during cleaning to prevent the buildup of fumes.

5.2.4 Documentation:

• Maintain a cleaning logbook to record all cleaning activities, including the date, time, area cleaned, cleaning agents used, and person performing the cleaning.

• Verify that the cleaning has been completed according to the SOP. The Production Supervisor reviews.

5.3 Area Room Cleaning in Warehouse

5.3.1 Frequency:

• Daily cleaning of dispensing booth.

• Weekly cleaning of quarantine area.

• Monthly cleaning of receiving and dispatch areas.

5.3.2 Materials and Equipment:

• Use dedicated cleaning equipment for each area to prevent cross-contamination.

• Use disposable wipes for cleaning surfaces in the dispensing booth.

• Use lint-free cloths for cleaning sensitive equipment.

• Equipment codes for material handling equipment include: STK-01 (Stacker).

5.3.3 Procedure:

5.3.3.1 Dispensing Booth:

• Remove all materials from the dispensing booth.

• Wipe down all surfaces with a validated disinfectant.

• Clean the floor with a vacuum cleaner or damp mop.

• Ensure that the air handling system is functioning properly.

• Document the cleaning in the dispensing booth cleaning logbook.

5.3.3.2 Quarantine Area:

• Remove all materials from the quarantine area.

• Sweep or vacuum the floor to remove loose dirt and debris.

• Wash the floor with an approved cleaning agent and water.

• Wipe down all surfaces with an approved cleaning agent.

• Ensure that the quarantine area is properly labeled and segregated.

5.3.3.3 Receiving and Dispatch Areas:

• Remove all materials from the receiving and dispatch areas.

• Sweep or vacuum the floor to remove loose dirt and debris.

• Wash the floor with an approved cleaning agent and water.

• Clean the loading docks and ramps.

• Ensure that the receiving and dispatch areas are properly ventilated.

5.3.4 Documentation:

• Maintain a cleaning logbook for each area to record all cleaning activities.

• Verify that the cleaning has been completed according to the SOP.

5.4 Entry and Exit Procedures for Warehouse Areas

5.4.1 General Requirements:

• All personnel entering the warehouse must wear appropriate personal protective equipment (PPE), including cleanroom gowns, gloves, and shoe covers.

• Visitors must be escorted by authorized personnel and must adhere to the same entry and exit procedures.

• Personnel must wash their hands thoroughly before entering the warehouse.

• Food, drinks, and smoking are prohibited in the warehouse.

5.4.2 Entry Procedure:

• Remove any personal belongings that are not required for work.

• Put on the required PPE in the designated changing area.

• Sanitize hands with an approved hand sanitizer.

• Enter the warehouse through the designated entrance.

• Sign in to the warehouse entry logbook.

5.4.3 Exit Procedure:

• Remove PPE in the designated changing area.

• Dispose of used PPE in the designated waste containers.

• Wash hands thoroughly with soap and water.

• Sign out of the warehouse entry logbook.

• Exit the warehouse through the designated exit.

5.4.4 Specific Area Requirements:

• Dispensing Booth: Additional PPE may be required, such as respirators or face shields.

• Quarantine Area: Access to the quarantine area is restricted to authorized personnel only.

• Receiving and Dispatch Areas: Personnel must follow specific procedures for handling materials and equipment.

5.4.5 Documentation:

• Maintain an entry logbook to record all entries and exits to the warehouse.

• Review the entry logbook regularly to ensure compliance with the SOP.

5.5 Temperature and Humidity Monitoring

5.5.1 Monitoring Equipment:

• Use calibrated temperature and humidity monitoring devices to continuously monitor the warehouse environment.

• Ensure that the monitoring devices are placed in representative locations throughout the warehouse.

• Use data loggers to automatically record temperature and humidity data.

• Calibrate monitoring devices according to a predetermined schedule.

5.5.2 Monitoring Frequency:

• Continuously monitor temperature and humidity.

• Review temperature and humidity data daily to identify any deviations from the acceptable range.

• Generate reports summarizing temperature and humidity data monthly.

5.5.3 Acceptable Range:

• Maintain temperature within the range of 15°C to 25°C.

• Maintain humidity within the range of 30% to 65% relative humidity.

• Specific storage conditions may be required for certain materials; refer to the material's storage requirements.

5.5.4 Corrective Action:

• In the event of a temperature or humidity excursion, investigate the cause of the excursion and implement corrective actions to restore the environment to the acceptable range.

• Quarantine any materials that may have been affected by the excursion.

• Document the excursion and the corrective actions taken.

5.5.5 Documentation:

• Maintain a temperature and humidity monitoring logbook to record all monitoring data, excursions, and corrective actions.

• Review temperature and humidity data regularly to identify trends and potential problems.

5.6 FIFO/FEFO Inventory Management

5.6.1 Implementation:

• Implement a FIFO/FEFO inventory management system to ensure that materials are used in the order in which they were received or based on their expiration date.

• Clearly label all materials with their receipt date and expiration date.

• Use a computerized inventory management system to track the location and status of all materials.

5.6.2 Procedure:

• When issuing materials, always select the materials with the earliest receipt date or expiration date.

• Rotate stock regularly to ensure that older materials are used before newer materials.

• Segregate expired materials from unexpired materials.

• Dispose of expired materials according to SOP-MM-012 (Waste Disposal).

5.6.3 Documentation:

• Maintain accurate inventory records to track the movement of materials through the warehouse.

• Review inventory records regularly to identify any discrepancies or potential problems.

5.7 Line Clearance

5.7.1 Procedure:

• Before starting a new production run, perform a line clearance to ensure that the production area is free of all materials from the previous run.

• Remove all materials, equipment, and documentation from the production area.

• Clean the production area according to the cleaning SOP.

• Inspect the production area to ensure that it is free of any residual materials.

• Document the line clearance in the production record.

5.7.2 Verification:

• The Production Supervisor verifies the line clearance before the start of the new production run.

• The QC Inspector may also verify the line clearance to ensure that it has been performed correctly.

6.0 SAFETY PRECAUTIONS

6.1 General Safety:

- All personnel must be trained in general safety procedures before working in the warehouse.

- Wear appropriate PPE at all times.

- Follow all safety rules and regulations.

- Report any accidents or injuries to the Production Supervisor immediately.

- Material Safety Data Sheets (MSDS) for all cleaning agents and pesticides must be readily available.

6.2 Chemical Handling:

- Handle all cleaning agents and pesticides with care.

- Follow the manufacturer's instructions for use.

- Store chemicals in a designated area.

- Use appropriate PPE when handling chemicals.

- In case of spills, clean up immediately according to the spill control procedure.

6.3 Equipment Safety:

- Operate all equipment according to the manufacturer's instructions.

- Inspect equipment before each use.

- Report any equipment malfunctions to the Production Supervisor immediately.

- Only trained and authorized personnel are permitted to operate equipment.

6.4 Emergency Procedures:

- Be familiar with the emergency evacuation plan.

- Know the location of fire extinguishers and other safety equipment.

- Report any fires or other emergencies to the emergency response team immediately.

7.0 DOCUMENTATION

7.1 The following records shall be maintained:

- Pest Control Logbook

- Cleaning Logbook

- Temperature and Humidity Monitoring Logbook

- Warehouse Entry Logbook

- Inventory Records

- Line Clearance Records

- Calibration Records for Monitoring Equipment

- Training Records for Personnel

• Deviations and Corrective Actions Log

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

7.3 All records shall be stored in a secure location and retained for a minimum of [Specify Retention Period – e.g., three years after batch expiry].

7.4 Electronic records shall be backed up regularly.

8.0 TRAINING

8.1 All personnel involved in the activities described in this SOP shall be trained on this SOP.

8.2 Training shall be conducted by qualified personnel.

8.3 Training shall be documented in the personnel training records.

8.4 Refresher training shall be conducted periodically to ensure that personnel remain competent.

9.0 ANNEXURES

9.1 Annexure 1: Pest Control Monitoring Form

9.2 Annexure 2: Warehouse Cleaning Checklist

9.3 Annexure 3: Temperature and Humidity Monitoring Chart

9.4 Annexure 4: Approved Cleaning Agents List

9.5 Annexure 5: List of Approved Pesticides

10.0 REVISION HISTORY

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

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1.0 | 2025-01-01 | Initial Release | New SOP | QA Manager

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Materials Management

Title: Waste Disposal

SOP No.: SOP-MM-012

Version No.: 1.0

Effective Date: 2025-01-01

1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to establish a systematic and compliant procedure for the collection, segregation, handling, and disposal of waste generated within the Materials Management department and warehouse of NovaThera Pharmaceuticals Pvt. Ltd., Pune, India. This SOP ensures compliance with Good Manufacturing Practices (GMP), environmental regulations, and safety standards.

2.0 SCOPE

This SOP applies to all personnel involved in the generation, handling, and disposal of waste materials within the Materials Management department and warehouse areas of NovaThera Pharmaceuticals Pvt. Ltd., including Warehouse Operators, QC Inspectors, Production Supervisors, and QA personnel. This includes all types of waste generated, such as expired raw materials, packaging materials, damaged goods, cleaning materials, and general waste.

3.0 RESPONSIBILITY

3.1 Warehouse Operator: Responsible for properly segregating and disposing of waste according to this SOP. They are responsible for promptly reporting any spills or unusual waste disposal incidents to the Production Supervisor.

3.2 Production Supervisor: Responsible for overseeing the implementation of this SOP, ensuring that all warehouse personnel are trained and competent in waste handling and disposal procedures. They are responsible for investigating and addressing any deviations or observations reported by the Warehouse Operator.

3.3 QC Inspector: Responsible for ensuring that waste disposal practices meet quality standards and do not pose a risk to product quality or the environment. The QC Inspector is responsible for reviewing waste disposal records and documentation.

3.4 QA Manager: Responsible for the overall implementation and compliance of this SOP. The QA Manager is responsible for approving revisions to this SOP and ensuring that it is aligned with GMP, environmental, and safety regulations. They also oversee audits of waste disposal practices.

4.0 DEFINITIONS

4.1 Waste: Any material that is no longer usable or required and is intended for disposal.

4.2 Hazardous Waste: Waste that poses a substantial or potential threat to public health or the environment. This may include toxic, corrosive, flammable, or reactive materials.

4.3 Non-Hazardous Waste: Waste that does not pose a significant threat to public health or the environment. This may include general office waste, packaging materials, and food waste.

4.4 Segregation: The process of separating different types of waste to facilitate proper handling and disposal.

4.5 Disposal: The final disposition of waste materials, either through recycling, incineration, landfill, or other approved methods.

4.6 MSDS: Material Safety Data Sheet; a document that provides information about the hazards of a particular chemical or material.

4.7 SOP: Standard Operating Procedure; a written procedure that describes how to perform a specific task.

5.0 PROCEDURE

5.1 Waste Segregation:

5.1.1 Types of Waste:

• Expired Raw Materials: Raw materials that have exceeded their expiration date.

• Damaged Packaging Materials: Packaging materials that are damaged or unusable.

• Rejected Materials: Materials that do not meet quality standards and are rejected for use.

• Cleaning Materials: Used cleaning cloths, mops, and other cleaning supplies.

• General Waste: Office paper, food waste, and other non-hazardous waste.

• Hazardous Waste: Solvents, chemicals, and other materials that pose a risk to public health or the environment.

5.1.2 Segregation Procedure:

• Separate waste into different categories based on its type and hazard level.

• Use clearly labeled containers for each type of waste.

• Ensure that containers are properly sealed to prevent leaks or spills.

• Place hazardous waste in containers that are specifically designed for hazardous materials.

• Keep hazardous and non-hazardous waste separate.

• Ensure that all containers are labeled with the type of waste they contain and the date of disposal.

5.2 Waste Handling:

5.2.1 Personal Protective Equipment (PPE):

• Wear appropriate PPE when handling waste, including gloves, safety glasses, and a lab coat or apron.

• Use respirators if handling hazardous waste that may release fumes or dust.

• Ensure that all PPE is in good condition and properly fitted.

5.2.2 Handling Procedure:

• Handle waste carefully to avoid spills or leaks.

• Use appropriate equipment for moving heavy or bulky waste containers (e.g., trolleys, forklifts).

• Follow the manufacturer's instructions for handling hazardous waste.

• Avoid mixing different types of waste.

• Clean up any spills immediately.

5.3 Waste Storage:

5.3.1 Designated Storage Area:

• Store waste in a designated area that is separate from storage areas for raw materials, packaging materials, and finished products.

• Ensure that the storage area is well-ventilated and protected from the elements.

• Keep the storage area clean and organized.

• Clearly label the storage area with signs indicating that it is a waste storage area.

5.3.2 Storage Requirements:

• Store hazardous waste in containers that are compatible with the waste material.

• Store flammable materials in fire-resistant cabinets.

• Keep containers tightly sealed to prevent leaks or spills.

• Inspect waste containers regularly for damage or leaks.

• Provide spill containment measures in the storage area (e.g., spill trays, absorbent materials).

5.4 Waste Disposal:

5.4.1 Approved Disposal Methods:

• Dispose of waste using approved methods that comply with local, state, and federal regulations.

• Recycle materials whenever possible.

• Incinerate hazardous waste in a permitted incinerator.

• Dispose of non-hazardous waste in a permitted landfill.

• Use a licensed waste disposal contractor to handle hazardous waste.

5.4.2 Disposal Procedure:

• Schedule waste disposal with the approved waste disposal contractor.

• Prepare a waste manifest for hazardous waste shipments.

• Ensure that the waste is properly labeled and packaged for transport.

• Supervise the loading of waste onto the transport vehicle.

• Obtain a signed copy of the waste manifest from the waste disposal contractor.

• Maintain records of all waste disposal activities.

5.5 Spill Control:

5.5.1 Spill Prevention:

• Take precautions to prevent spills during waste handling and storage.

• Use appropriate equipment for transferring liquids.

• Inspect waste containers regularly for leaks.

• Train personnel on spill prevention measures.

5.5.2 Spill Response:

• In the event of a spill, take immediate action to contain the spill and prevent it from spreading.

• Use absorbent materials to soak up spilled liquids.

• Clean up the spill area with an appropriate cleaning agent.

• Dispose of contaminated materials properly.

• Report the spill to the Production Supervisor and QA Manager.

5.6 Documentation:

5.6.1 Waste Disposal Log:

• Maintain a waste disposal log to record all waste disposal activities.

• Include the following information in the log:

• Date of disposal

• Type of waste

• Quantity of waste

• Disposal method

• Waste disposal contractor

• Waste manifest number

• Signature of the person responsible for disposal

5.6.2 Waste Manifests:

• Retain copies of all waste manifests for hazardous waste shipments.

• Ensure that the manifests are properly completed and signed.

• Store the manifests in a secure location.

5.6.3 Training Records:

- Maintain records of all training on waste handling and disposal procedures.
- Include the following information in the training records:
- Date of training
- Topics covered
- Names of personnel trained
- Signature of the trainer

6.0 SAFETY PRECAUTIONS

6.1 General Safety:

- All personnel must be trained in general safety procedures before handling waste.
- Wear appropriate PPE at all times.
- Follow all safety rules and regulations.
- Report any accidents or injuries to the Production Supervisor immediately.
- Know the location of fire extinguishers and other safety equipment.

6.2 Hazardous Waste Handling:

- Handle hazardous waste with care.
- Follow the manufacturer's instructions for use.
- Store hazardous waste in a designated area.
- Use appropriate PPE when handling hazardous waste.
- In case of spills, clean up immediately according to the spill control procedure.
- Consult the MSDS for specific handling and disposal instructions.

6.3 Emergency Procedures:

- Be familiar with the emergency evacuation plan.
- Know the location of fire extinguishers and other safety equipment.
- Report any fires or other emergencies to the emergency response team immediately.
- Know the location of the nearest eyewash station and safety shower.

7.0 DOCUMENTATION

7.1 The following records shall be maintained:

- Waste Disposal Log
- Waste Manifests
- Training Records for Personnel on Waste Handling
- Inspection Records of Waste Storage Areas

- • Records of any Spills and Corrective Actions Taken

- • Vendor Qualifications for Waste Disposal Contractors

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

7.3 All records shall be stored in a secure location and retained for a minimum of [Specify Retention Period – e.g., three years after batch expiry].

7.4 Electronic records shall be backed up regularly.

8.0 TRAINING

8.1 All personnel involved in the activities described in this SOP shall be trained on this SOP.

8.2 Training shall be conducted by qualified personnel.

8.3 Training shall be documented in the personnel training records.

8.4 Refresher training shall be conducted periodically to ensure that personnel remain competent.

9.0 ANNEXURES

9.1 Annexure 1: Waste Segregation Chart

9.2 Annexure 2: Waste Disposal Log Form

9.3 Annexure 3: Spill Response Procedure

9.4 Annexure 4: Approved Waste Disposal Contractors List

9.5 Annexure 5: Hazardous Waste Handling Guidelines

10.0 REVISION HISTORY

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

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1.0 | 2025-01-01 | Initial Release | New SOP | QA Manager

Document Approval

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

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