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Storage and Handling of Approved Materials

Category: Materials Management

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

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 proper storage and handling of approved materials (Raw Materials and Packing Materials) at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India, to ensure their quality, safety, and integrity, and to comply with Good Manufacturing Practices (GMP) and applicable regulatory guidelines. This SOP covers receipt, quarantine, sampling, storage, handling, and dispatch of approved materials. It also includes procedures for temperature and humidity monitoring, cleaning and maintenance of the warehouse, and inter-location transfer of materials.

2.0 SCOPE

This SOP applies to all personnel involved in the receipt, storage, handling, sampling, and dispatch of approved raw materials and packaging materials within the Materials Management Department at NovaThera Pharmaceuticals Pvt. Ltd. This includes, but is not limited to, Warehouse Operators, QC Inspectors, Production Supervisors, and the QA Manager. This SOP covers approved materials used in the manufacturing of pharmaceutical products at the facility.

3.0 RESPONSIBILITIES

3.1 Warehouse Operator: Responsible for the execution of the procedures outlined in this SOP, including the receipt, storage, handling, sampling, and dispatch of approved materials. They are also

responsible for maintaining the cleanliness of the warehouse and reporting any deviations to the Production Supervisor and QA Manager.

3.2 QC Inspector: Responsible for the inspection and sampling of approved materials as per approved sampling plans and standard testing procedures. They are also responsible for releasing approved materials into the dispensing booth and ensuring proper documentation.

3.3 Production Supervisor: Responsible for overseeing the activities of the Warehouse Operators and ensuring that the procedures outlined in this SOP are followed. They are also responsible for investigating deviations and implementing corrective and preventive actions (CAPA).

3.4 QA Manager: Responsible for the overall compliance of the Materials Management Department with GMP and applicable regulatory guidelines. They are responsible for approving this SOP, reviewing deviations, and ensuring that CAPA are implemented effectively. The QA Manager is also responsible for auditing the Materials Management Department to ensure compliance with this SOP.

4.0 DEFINITIONS

4.1 Approved Material: Raw materials and packaging materials that have been sampled, tested, and approved by Quality Control for use in the manufacturing of pharmaceutical products.

4.2 Quarantine Area: A designated area within the warehouse where incoming materials are held pending inspection and testing by Quality Control.

4.3 Released Area: A designated area within the warehouse where approved materials are stored after being released by Quality Control.

4.4 Rejected Area: A designated area within the warehouse where rejected materials are stored pending disposal.

4.5 FIFO: First In, First Out. An inventory management principle where the oldest materials are used first.

4.6 FEFO: First Expired, First Out. An inventory management principle where the materials with the earliest expiration date are used first.

4.7 Temperature Excursion: Any deviation from the established temperature range for the storage of approved materials.

4.8 Relative Humidity: The amount of moisture in the air compared to the maximum amount of moisture the air can hold at a specific temperature.

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

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

5.0 PROCEDURE

5.1 Receipt of Approved Materials

5.1.1 Upon arrival of a shipment of approved materials, the Warehouse Operator shall verify the following:

• The delivery documents (e.g., purchase order, packing list, certificate of analysis) match the materials received.

• The materials are properly labeled with the correct product name, batch number, and quantity.

• The materials are not damaged or compromised.

• The temperature monitoring device (if any) indicates that the materials were stored within the required temperature range during transit.

5.1.2 Any discrepancies or deviations shall be reported to the Production Supervisor and QA Manager immediately.

5.1.3 The Warehouse Operator shall record the receipt of the materials in the Material Receipt Log. The log should contain all relevant information, including date of receipt, supplier name, material name, batch number, quantity received, and any deviations noted.

5.1.4 The materials shall be assigned a unique internal identification number (Material ID).

5.1.5 The received materials shall be transferred to the designated Quarantine Area using appropriate material handling equipment (e.g., BLN-04, TCP-01).

5.1.6 A "Quarantine" label shall be affixed to each container of the received materials.

5.2 Quarantine and Sampling

5.2.1 Materials in the Quarantine Area shall be held pending inspection and sampling by the QC Inspector.

5.2.2 The QC Inspector shall inspect the materials for any signs of damage, contamination, or other deviations.

5.2.3 The QC Inspector shall collect samples of the materials according to the approved sampling plan.

5.2.4 Samples shall be labeled with the material name, batch number, Material ID, date of sampling, and the name of the QC Inspector.

5.2.5 The QC Inspector shall record the sampling information in the Material Sampling Log.

5.2.6 The sampled materials shall remain in the Quarantine Area until the QC Inspector releases them.

5.3 Storage of Approved Materials

5.3.1 Upon release of the materials by the QC Inspector, the Warehouse Operator shall transfer the materials from the Quarantine Area to the designated Released Area using appropriate material handling equipment (e.g., BLN-04, TCP-01, STK-01).

5.3.2 The Warehouse Operator shall ensure that the materials are stored in accordance with the manufacturer's recommendations and the requirements outlined in the Material Safety Data Sheet (MSDS).

5.3.3 The Warehouse Operator shall ensure that the materials are stored in a clean, dry, and well-ventilated area.

5.3.4 The Warehouse Operator shall ensure that the materials are stored in a manner that prevents damage or contamination.

5.3.5 The Warehouse Operator shall ensure that the materials are stored in a manner that allows for easy access and retrieval.

5.3.6 The Warehouse Operator shall ensure that the materials are stored in a manner that facilitates FIFO/FEFO inventory management.

5.3.7 The Warehouse Operator shall use appropriate shelving and racking systems (e.g., SFT-02) to maximize storage space and ensure the stability of the stored materials.

5.3.8 The Warehouse Operator shall affix a "Released" label to each container of the approved materials.

5.3.9 Store hazardous materials as per approved procedure and ensure proper segregation.

5.4 Handling of Approved Materials

5.4.1 The Warehouse Operator shall handle approved materials with care to prevent damage or contamination.

5.4.2 The Warehouse Operator shall use appropriate material handling equipment (e.g., BLN-04, TCP-01) to move approved materials.

5.4.3 The Warehouse Operator shall wear appropriate personal protective equipment (PPE), such as gloves, safety glasses, and respiratory protection, when handling approved materials. Refer to the MSDS for specific PPE requirements.

5.4.4 The Warehouse Operator shall ensure that all handling equipment is clean and in good working order.

5.4.5 The Warehouse Operator shall follow proper lifting techniques to prevent injuries.

5.4.6 The Warehouse Operator shall immediately clean up any spills or leaks of approved materials.

5.5 Dispatch of Approved Materials

5.5.1 Upon receipt of a material requisition from the Production Department, the Warehouse Operator shall retrieve the required materials from the Released Area using appropriate material handling equipment (e.g., BLN-04, TCP-01, STK-01).

5.5.2 The Warehouse Operator shall verify that the materials retrieved match the materials requested on the material requisition.

5.5.3 The Warehouse Operator shall dispense the required quantity of materials.

5.5.4 The Warehouse Operator shall record the dispatch of the materials in the Material Dispatch Log.

5.5.5 The Warehouse Operator shall transfer the dispatched materials to the designated dispensing booth or production area.

5.5.6 The Warehouse Operator shall ensure that the dispatched materials are properly labeled with the material name, batch number, quantity dispatched, and date of dispatch.

5.5.7 The QC Inspector will verify the material dispatch and release it to the production area.

5.6 Monitoring of Temperature, Relative Humidity, and Differential Pressure

5.6.1 The temperature and relative humidity in the warehouse shall be monitored continuously using calibrated temperature and humidity monitoring devices (e.g., electronic data loggers).

5.6.2 The temperature and relative humidity shall be recorded at least twice daily, or as per defined frequency in respective procedures.

5.6.3 The temperature and relative humidity shall be maintained within the established limits as per material storage requirements.

5.6.4 Any temperature or humidity excursions shall be reported to the Production Supervisor and QA Manager immediately.

5.6.5 A written record of all temperature and humidity readings shall be maintained.

5.6.6 Differential pressure between warehouse areas shall be monitored using calibrated pressure gauges.

5.6.7 Differential pressure shall be maintained as per defined limits to prevent contamination.

5.6.8 Regular calibration of temperature, humidity, and pressure monitoring devices will be performed as per approved schedule.

5.7 Cleaning and Maintenance

5.7.1 The warehouse shall be cleaned regularly according to a written cleaning schedule.

5.7.2 The cleaning schedule shall specify the frequency of cleaning, the cleaning agents to be used, and the cleaning procedures to be followed.

5.7.3 The cleaning agents used shall be appropriate for the materials stored in the warehouse and shall not leave any residue that could contaminate the materials.

5.7.4 The warehouse shall be inspected regularly for any signs of pests or rodents.

5.7.5 Pest control measures shall be implemented as necessary to prevent infestation.

5.7.6 Material handling equipment shall be maintained regularly to ensure that it is in good working order.

5.7.7 A written record of all cleaning and maintenance activities shall be maintained.

5.8 Inter-Location Transfer of Materials

5.8.1 When materials need to be transferred between different locations within NovaThera Pharmaceuticals Pvt. Ltd. (e.g., from the main warehouse to a satellite warehouse), the following procedure shall be followed:

• A material transfer request shall be initiated by the requesting department and approved by the Production Supervisor.

• The Warehouse Operator shall retrieve the required materials from the originating location.

• The Warehouse Operator shall verify that the materials retrieved match the materials requested on the material transfer request.

• The Warehouse Operator shall package the materials appropriately for transport to prevent damage or contamination.

• The Warehouse Operator shall label the packages with the material name, batch number, quantity transferred, originating location, destination location, and date of transfer.

• The materials shall be transported using appropriate transportation equipment.

• The Warehouse Operator at the receiving location shall verify that the materials received match the materials listed on the material transfer request.

• The Warehouse Operator at the receiving location shall record the receipt of the materials in the Material Transfer Log.

• The QA Manager shall be notified of the material transfer.

• The QC inspector at the receiving location shall inspect the materials for damage before putting them into storage.

• Any discrepancies should be immediately reported to the QA Manager

5.9 Line Clearance and Dispensing Booth Operations

5.9.1 After dispensing of raw materials from the dispensing booth, a thorough line clearance shall be performed by the Warehouse Operator.

5.9.2 The Warehouse Operator shall ensure that all remaining materials, containers, and equipment are removed from the dispensing booth.

5.9.3 The Warehouse Operator shall clean the dispensing booth according to the approved cleaning procedure.

5.9.4 The Warehouse Operator shall document the line clearance activities in the Line Clearance Log.

5.9.5 The dispensing booth shall be inspected by the QC Inspector to ensure that it is clean and ready for the next dispensing operation.

6.0 DOCUMENTATION

6.1 Material Receipt Log

6.2 Material Sampling Log

6.3 Material Dispatch Log

6.4 Temperature and Humidity Monitoring Log

6.5 Cleaning and Maintenance Log

6.6 Material Transfer Log

6.7 Line Clearance Log

6.8 Deviations and CAPA Records

All records shall be maintained in accordance with NovaThera Pharmaceuticals Pvt. Ltd.'s record retention policy. All entries in the logs shall be legible, accurate, and complete. All entries shall be signed and dated by the person making the entry. Any corrections to the logs shall be made by drawing a single line through the incorrect entry, writing the correct entry, and initialing and dating the correction.

7.0 SAFETY PRECAUTIONS

7.1 All personnel shall be trained on the safe handling of approved materials and the use of material handling equipment.

7.2 All personnel shall wear appropriate personal protective equipment (PPE) when handling approved materials. Refer to the MSDS for specific PPE requirements.

7.3 All material handling equipment shall be inspected regularly to ensure that it is in good working order.

7.4 All spills or leaks of approved materials shall be cleaned up immediately.

7.5 Emergency contact information shall be posted in a prominent location in the warehouse.

7.6 Material Safety Data Sheets (MSDS) shall be readily available for all approved materials.

7.7 Adequate ventilation shall be provided in the warehouse to prevent the buildup of hazardous fumes.

7.8 Fire extinguishers shall be readily available and properly maintained.

7.9 Regular safety audits shall be conducted to identify and address potential safety hazards.

8.0 ENVIRONMENTAL CONTROLS

8.1 The warehouse shall be designed and operated to minimize the impact on the environment.

8.2 Waste materials shall be disposed of in accordance with applicable environmental regulations.

8.3 Spills and leaks shall be contained and cleaned up promptly to prevent environmental contamination.

8.4 Energy consumption shall be minimized through the use of energy-efficient lighting and equipment.

8.5 Water conservation measures shall be implemented.

8.6 Regular environmental audits shall be conducted to ensure compliance with environmental regulations.

9.0 ANNEXURES

9.1 Material Receipt Log Template

9.2 Material Sampling Log Template

9.3 Material Dispatch Log Template

9.4 Temperature and Humidity Monitoring Log Template

9.5 Cleaning and Maintenance Log Template

9.6 Material Transfer Log Template

9.7 Line Clearance Log Template

10.0 REVISION HISTORY

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

Prepared By: [Role: Materials Management Specialist]

Reviewed By: [Role: Production Supervisor]

Approved By: [Role: QA Manager]

Document Approval

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Prepared by:	_____	_____	_____
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