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Title:	Handling of In-Process Materials and Batch Segregation	**Version:**	1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
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Handling of In-Process Materials and Batch Segregation

Category: Production/Manufacturing

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Production

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1.0 PURPOSE

This procedure defines the requirements for the proper handling, storage, and segregation of in-process materials during pharmaceutical manufacturing at NovaThera Pharmaceuticals Pvt. Ltd. This SOP ensures the prevention of mix-ups, contamination, and cross-contamination, maintaining the integrity and quality of all in-process materials according to Good Manufacturing Practices (GMP).

2.0 SCOPE

This SOP applies to all personnel involved in the handling, storage, movement, and segregation of in-process materials, including but not limited to raw materials after dispensing, partially processed materials, intermediates, bulk products awaiting packaging, rejected materials, and rework materials within the production areas of NovaThera Pharmaceuticals Pvt. Ltd. This procedure is applicable to all products and batches manufactured at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India. It does not cover the handling of finished goods after packaging.

3.0 RESPONSIBILITY

QC Inspector:

- Inspects and verifies the labeling and storage conditions of in-process materials.
- Performs sampling of in-process materials as per the approved sampling plan.
- Documents inspection and sampling activities in the relevant batch records and logbooks.
- Reports any deviations or discrepancies to the Production Supervisor and QA Manager.

Production Supervisor:

- Ensures that all personnel involved in handling in-process materials are trained and competent.
- Oversees the correct execution of this SOP.
- Ensures proper labeling, storage, and movement of in-process materials.
- Investigates and resolves any deviations or discrepancies related to in-process material handling.
- Approves the movement of in-process materials between different stages of manufacturing.
- Maintains accurate records of material movements and storage locations.

QA Manager:

- Reviews and approves this SOP and any revisions.
- Monitors the implementation of this SOP and ensures compliance with GMP regulations.
- Provides guidance and support to the Production Supervisor on matters related to in-process material handling.
- Investigates and approves deviations related to in-process material handling, in conjunction with the Head of QA.
- Conducts periodic audits to verify compliance with this SOP.

Head of QA:

- Provides final approval for this SOP and any revisions.
- Oversees the overall quality system related to in-process material handling.
- Ensures that adequate resources are available for the effective implementation of this SOP.
- Makes final decisions on deviations and investigations related to in-process material handling.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses
- Gloves (nitrile or latex, as appropriate)
- Lab coats
- Dust masks (as required)
- Safety shoes

Equipment:

- Pallet trucks
- Forklifts (certified operators only)
- Weighing scales (calibrated, with equipment code WSC-01, WSC-02)
- Temperature and humidity monitoring devices (THM-01)
- Transport containers (designated and labeled)
- Blender (BLN-04)
- Tablet Press (TCP-01)
- Sifter (SFT-02)

Documentation:

- Batch Manufacturing Records (BMR)
- Material Transfer Forms (MTF)
- Equipment Cleaning Logs
- Deviation Reports
- Training Records
- In-Process Material Logbook
- Storage Location Register

5.0 PROCEDURE

5.1 Material Receipt and Identification

5.1.1 Upon receipt of dispensed raw materials or materials from previous manufacturing steps, the Production Supervisor or designated personnel must verify the material against the Batch Manufacturing Record (BMR).

5.1.2 The QC Inspector verifies the identity and quantity of the material, confirming it matches the BMR requirements.

5.1.3 The QC Inspector affixes a "Released" or "Quarantine" label to the container based on the status indicated on the dispensing record or previous process step documentation.

5.1.4 The Production Supervisor ensures that each container is clearly labeled with the following information:

- Material Name and Grade
- Batch Number
- Stage of Manufacturing (e.g., "Dispensed Raw Material," "Granulation," "Compression")
- Quantity
- Date of Receipt
- Storage Requirements (e.g., "Store at Controlled Room Temperature")

5.1.5 The Production Supervisor records the receipt of the material in the In-Process Material Logbook, including all relevant information.

5.2 Storage of In-Process Materials

5.2.1 The Production Supervisor ensures that in-process materials are stored in designated storage areas, separated from raw materials and finished goods.

5.2.2 Each storage area must be clearly identified with signage indicating its purpose (e.g., "Quarantine Area," "Released In-Process Materials").

5.2.3 Materials under "Quarantine" status must be physically segregated from "Released" materials.

5.2.4 Storage areas must be maintained at appropriate temperature and humidity conditions, as specified in the BMR and material specifications. Temperature and humidity monitoring devices (THM-01) must be checked and recorded daily.

5.2.5 Materials must be stored in a manner that prevents damage or contamination. Pallets must be used to elevate containers off the floor.

5.2.6 The Production Supervisor ensures that the Storage Location Register is updated with the location of each in-process material container.

5.2.7 First-In, First-Out (FIFO) principle should be followed for materials with expiration dates or retest dates.

5.2.8 In-process materials from different batches must be clearly segregated to prevent mix-ups. Physical barriers or sufficient spacing must be maintained.

5.3 Movement of In-Process Materials

5.3.1 All movements of in-process materials must be documented using a Material Transfer Form (MTF).

5.3.2 The MTF must include the following information:

- Material Name and Grade
- Batch Number
- Quantity
- Originating Location
- Destination Location
- Date and Time of Transfer
- Name and Signature of person transferring the material
- Name and Signature of person receiving the material

5.3.3 The Production Supervisor must approve the MTF before any material is moved.

5.3.4 The person transferring the material is responsible for ensuring that the material is properly labeled and transported in a manner that prevents damage or contamination.

5.3.5 Upon receipt of the material at the destination location, the receiving personnel must verify the material against the MTF and confirm that it is in good condition.

5.3.6 The MTF must be retained with the Batch Manufacturing Record.

5.3.7 Forklifts (operated by certified personnel only) or pallet trucks are to be used for moving heavy or bulky materials.

5.3.8 Prior to moving any material, the transport route must be inspected for obstructions or potential hazards.

5.4 Handling During Manufacturing Processes

5.4.1 During manufacturing processes (e.g., blending using BLN-04, granulation, compression using TCP-01, sifting using SFT-02), materials must be handled in a manner that prevents contamination or mix-ups.

5.4.2 Dedicated equipment and utensils must be used for each product to prevent cross-contamination.

5.4.3 Equipment must be cleaned and sanitized according to the equipment cleaning SOP before and after each batch.

5.4.4 Materials must be protected from environmental contamination during processing. If processing requires open containers, it must be conducted in a controlled environment.

5.4.5 Samples of in-process materials must be taken by the QC Inspector according to the approved sampling plan and tested for relevant quality attributes.

5.4.6 In-process testing results must be documented in the BMR.

5.4.7 If in-process testing results are outside of the specified limits, the Production Supervisor must initiate a deviation investigation.

5.5 Management of Rejected Materials

5.5.1 Any in-process material that does not meet the required specifications must be designated as "Rejected."

5.5.2 Rejected materials must be physically segregated from other in-process materials and clearly labeled as "Rejected."

5.5.3 The Production Supervisor must initiate a deviation investigation to determine the cause of the rejection.

5.5.4 The QA Manager and Head of QA must approve the disposition of rejected materials (e.g., rework, reprocessing, or disposal).

5.5.5 The disposition of rejected materials must be documented in the BMR and a Deviation Report.

5.5.6 If rejected material is reworked or reprocessed, it must be clearly identified as such and subjected to additional testing to ensure it meets the required specifications.

5.6 Batch Segregation

5.6.1 Physical segregation of batches is critical to prevent mix-ups.

5.6.2 Dedicated rooms or areas should be used for different batches whenever possible.

5.6.3 If multiple batches are processed in the same area, they must be clearly identified and separated by physical barriers or sufficient spacing.

5.6.4 Equipment used for one batch must be thoroughly cleaned and sanitized before being used for another batch.

5.6.5 Documentation (BMRs, labels, etc.) must be kept separate for each batch.

5.6.6 During sampling, use separate sampling tools and containers for each batch.

5.6.7 At the completion of each manufacturing stage, all materials pertaining to that batch must be moved to the designated storage area. The area must be cleared and inspected by the Production Supervisor before another batch can be started in the same area.

6.0 POST-ACTIVITY ACTIVITIES

6.1 After the completion of each manufacturing step or batch, the Production Supervisor verifies that all in-process materials have been properly labeled, stored, and documented.

6.2 The Production Supervisor reviews the BMR to ensure that all entries are complete and accurate.

6.3 The QC Inspector performs a final inspection of the storage areas to verify that materials are properly segregated and stored under the correct conditions.

6.4 All documentation related to the batch (BMR, MTFs, Deviation Reports, etc.) is compiled and submitted to the QA department for review and approval.

6.5 The Production Supervisor ensures that the manufacturing area is cleaned and sanitized according to the cleaning SOP.

7.0 SAFETY PRECAUTIONS

7.1 All personnel must wear appropriate PPE (safety glasses, gloves, lab coats, dust masks, safety shoes) when handling in-process materials.

7.2 Avoid direct contact with in-process materials.

7.3 Follow proper lifting techniques to prevent injuries.

7.4 Use caution when operating pallet trucks and forklifts. Only certified personnel are allowed to operate forklifts.

7.5 Be aware of potential hazards associated with specific materials (e.g., flammable solvents, corrosive chemicals).

7.6 Read and understand the Material Safety Data Sheet (MSDS) for each material before handling it.

7.7 In case of spills or leaks, follow the established spill control procedures.

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

7.9 Ensure adequate ventilation in the manufacturing areas.

7.10 Emergency eyewash stations and safety showers must be readily accessible.

8.0 APPROVALS

Prepared By: Production Supervisor

Reviewed By: QA Manager

Approved By: Head of QA

Date:

Document Approval

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

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