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Dispensing of Raw Materials for Production

Category: Materials Management

Standard Operating Procedure (SOP)

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Department: Materials Management

Title: Dispensing of Raw Materials for Production

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1.0 PURPOSE

This Standard Operating Procedure (SOP) outlines the procedure for dispensing of raw materials required for the manufacturing of pharmaceutical products at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India. This SOP ensures that all raw materials are dispensed accurately, safely, and in compliance with Good Manufacturing Practices (GMP) and regulatory guidelines. This SOP covers the dispensing of both API (Active Pharmaceutical Ingredients) and excipients, as well as non-sterile raw materials and packing materials. This SOP also outlines the process for dispensing raw materials to the production area.

2.0 SCOPE

This SOP applies to all personnel involved in the dispensing of raw materials, including Warehouse Operators, QC Inspectors, and Production Supervisors, working within the Materials Management department of NovaThera Pharmaceuticals Pvt. Ltd. It covers all aspects of raw material dispensing, from the verification of material identity to the transfer of dispensed materials to the production area. This includes but is not limited to APIs, excipients, processing aids, and primary packaging materials.

3.0 RESPONSIBILITY

3.1 Warehouse Operator: Responsible for performing the dispensing process as per this SOP, ensuring accurate weighing, and maintaining cleanliness of the dispensing area.

3.2 QC Inspector: Responsible for verifying the identity, quantity, and integrity of raw materials before and after dispensing, and for releasing the dispensed materials for production.

3.3 Production Supervisor: Responsible for coordinating with the Warehouse Operator for material dispensing requirements and ensuring the correct materials are received in the production area.

3.4 QA Manager: Responsible for reviewing and approving this SOP, ensuring compliance with GMP regulations, and for investigating any deviations from this SOP.

4.0 DEFINITIONS

4.1 API: Active Pharmaceutical Ingredient.

4.2 Excipient: An inactive substance formulated alongside the active ingredient of a medication, for the purpose of bulking-up formulations that contain potent active ingredients (thus often referred to as "bulking agents", "fillers", or "diluents"), or to confer a therapeutic enhancement on the active ingredient in the final dosage form, such as facilitating drug absorption, reducing viscosity, or enhancing long-term stability.

4.3 FEFO: First Expired, First Out. Inventory management method.

4.4 FIFO: First In, First Out. Inventory management method.

4.5 Dispensing Booth: A controlled environment within the warehouse designed for dispensing raw materials, equipped with air handling systems to minimize particulate contamination.

4.6 Line Clearance: The process of removing all materials, documents, and waste from a dispensing area or production line before starting a new dispensing or manufacturing operation.

4.7 GMP: Good Manufacturing Practices.

4.8 MSDS: Material Safety Data Sheet. (Now called SDS - Safety Data Sheet)

4.9 SOP: Standard Operating Procedure.

4.10 TCP-01: Temperature and Humidity Chart Printer - ID

4.11 BLN-04: Weigh Balance - ID

4.12 SFT-02: Stackers- ID

4.13 STK-01: Forklift- ID

5.0 PROCEDURE

5.1 Pre-Dispensing Activities

5.1.1 Material Request: The Production Supervisor shall submit a written material request to the Materials Management department, specifying the raw materials required, the quantity needed, the batch number for which the

materials are required, and the date of dispensing.

5.1.2 Material Availability Check: The Warehouse Operator shall verify the availability of the requested raw materials in the warehouse using the inventory management system. The Warehouse Operator shall prioritize materials based on FEFO/FIFO principles.

5.1.3 Material Selection: The Warehouse Operator shall select the required raw materials from the designated storage location, ensuring the material identification label matches the material requested on the material request form.

5.1.4 Material Inspection: The Warehouse Operator, along with the QC Inspector, shall inspect the selected raw materials for any signs of damage, contamination, or expiry. The QC Inspector will verify the material's Certificate of Analysis (COA) against the material specification.

5.1.5 Dispensing Area Preparation: The Warehouse Operator shall ensure the dispensing area, including the dispensing booth (if applicable), is clean and free from any materials or debris from previous dispensing operations. Record cleaning in Equipment Cleaning Log Book.

5.1.6 Equipment Calibration: The Warehouse Operator shall verify that the weighing balances (BLN-04) are calibrated and in good working order. Calibration records should be readily available.

5.1.7 Dispensing Booth Preparation (If Applicable):

5.1.7.1 Ensure the dispensing booth is operational and the air handling system is functioning correctly.

5.1.7.2 Check the differential pressure of the dispensing booth and record it in the dispensing booth logbook. The pressure should be maintained as per

the defined specifications.

5.1.7.3 Clean the dispensing booth surfaces with approved cleaning agents before commencing dispensing operations. Record cleaning in Equipment Cleaning Log Book.

5.1.7.4 Ensure proper lighting is available inside the booth.

5.2 Dispensing Process

5.2.1 Personal Protective Equipment (PPE): The Warehouse Operator shall wear appropriate PPE, including but not limited to gloves, masks, eye protection, and lab coats, as specified in the site's safety guidelines and the MSDS (SDS) for each material.

5.2.2 Material Transfer: The Warehouse Operator shall transfer the raw materials to the dispensing area using appropriate equipment, such as hand trucks or pallet jacks (STK-01), ensuring the materials are handled carefully to prevent damage or contamination.

5.2.3 Verification: The Warehouse Operator shall re-verify the identity of the raw material against the material request form and the material label. The QC Inspector shall also verify the same.

5.2.4 Weighing:

5.2.4.1 The Warehouse Operator shall accurately weigh the required quantity of the raw material using the calibrated weighing balance (BLN-04).

5.2.4.2 The weighing process shall be conducted carefully to avoid spillage or contamination.

5.2.4.3 The weight shall be recorded on the dispensing label and initialed by the Warehouse Operator.

5.2.4.4 The QC Inspector shall verify the weight and initial the dispensing label.

5.2.5 Container Labeling:

5.2.5.1 The dispensed raw material shall be placed in a clean, appropriately sized container.

5.2.5.2 The container shall be labeled with the following information:

- Material Name
- Batch Number
- Quantity Dispensed
- Date of Dispensing
- Dispensing SOP Number
- Dispensing Weight.
- Warehouse Operator's Initials
- QC Inspector’s Initials

5.2.6 Segregation: The dispensed raw materials shall be segregated from the undispensed raw materials to prevent mix-ups.

5.3 Post-Dispensing Activities

5.3.1 Material Reconciliation: The Warehouse Operator shall reconcile the quantity of raw material dispensed with the quantity remaining in the original container. Any discrepancies shall be investigated and documented.

5.3.2 Material Return: The remaining raw material in the original container shall be returned to its designated storage location, ensuring proper

labeling and storage conditions.

5.3.3 Documentation: The Warehouse Operator shall complete the dispensing record, including the following information:

- Material Name
- Batch Number
- Quantity Requested
- Quantity Dispensed
- Date of Dispensing
- Dispensing SOP Number
- Weighing Balance ID (BLN-04)
- Warehouse Operator's Signature
- QC Inspector's Signature

5.3.4 Dispensing Area Cleaning: The Warehouse Operator shall clean the dispensing area, including the weighing balance and dispensing booth (if applicable), with approved cleaning agents. Record cleaning in Equipment Cleaning Log Book.

5.3.5 Waste Disposal: All waste materials, including used gloves, masks, and empty containers, shall be disposed of according to the site's waste management procedures.

5.3.6 Material Release: The QC Inspector shall review the dispensing record and verify the accuracy of the dispensing process. The QC Inspector shall then release the dispensed raw materials for production.

5.4 Dispensing of Raw Materials to Production Area

5.4.1 Transportation: The dispensed raw materials shall be transported to the production area in a secure and controlled manner, using appropriate equipment such as hand trucks or pallet jacks (STK-01).

5.4.2 Documentation: A transfer document shall accompany the dispensed raw materials, including the following information:

- Material Name
- Batch Number
- Quantity Dispensed
- Date of Dispensing
- Dispensing SOP Number
- Warehouse Operator's Signature
- QC Inspector's Signature
- Production Supervisor’s Signature (acknowledging receipt)

5.4.3 Verification: The Production Supervisor shall verify the identity and quantity of the dispensed raw materials against the transfer document upon receipt in the production area.

5.4.4 Storage: The dispensed raw materials shall be stored in a designated area within the production area, ensuring proper labeling and storage conditions.

5.5 Dispensing of Non-Sterile Raw Material

5.5.1 This procedure applies to all non-sterile raw materials used in the manufacturing process.

5.5.2 All steps outlined in Sections 5.1, 5.2, 5.3, and 5.4 of this SOP shall be followed for dispensing non-sterile raw materials.

5.5.3 Additional precautions shall be taken to prevent contamination of non-sterile raw materials, including:

- Ensuring the dispensing area is thoroughly cleaned before dispensing. Record cleaning in Equipment Cleaning Log Book.
- Using dedicated dispensing equipment for non-sterile raw materials.
- Wearing appropriate PPE to minimize the risk of contamination.

5.6 Dispensing of API & Excipients

5.6.1 This procedure applies to both API and excipients used in the manufacturing process.

5.6.2 All steps outlined in Sections 5.1, 5.2, 5.3, and 5.4 of this SOP shall be followed for dispensing API and excipients.

5.6.3 Additional precautions shall be taken when dispensing API and excipients, including:

• Reviewing the MSDS (SDS) for each material to understand the potential hazards and required safety precautions.

• Using appropriate containment measures, such as dispensing booths or local exhaust ventilation, to minimize exposure to hazardous materials.

• Following specific handling instructions for potent APIs to prevent cross-contamination.

5.7 Line Clearance for Dispensing of Packing Material

5.7.1 Before dispensing packing materials, a line clearance shall be performed to ensure the dispensing area is free from any materials or debris from previous operations.

5.7.2 The line clearance procedure shall include the following steps:

• Removing all materials, documents, and waste from the dispensing area.

• Inspecting the dispensing area for any remaining materials or debris.

• Cleaning the dispensing area with approved cleaning agents. Record cleaning in Equipment Cleaning Log Book.

• Documenting the line clearance process in the dispensing record.

• QC Inspector verification of clean lines.

5.7.3 The Warehouse Operator and QC Inspector shall sign the line clearance checklist to confirm that the dispensing area is clear and ready for dispensing packing materials.

6.0 TEMPERATURE AND HUMIDITY MONITORING

6.1 Temperature and humidity monitoring shall be performed in the warehouse and dispensing areas to ensure that raw materials are stored and dispensed under appropriate conditions.

6.2 Temperature and humidity levels shall be monitored continuously using calibrated temperature and humidity monitoring devices.

6.3 Temperature and humidity data shall be recorded at defined intervals and reviewed regularly. Use TCP-01 (Temperature and Humidity Chart Printer)

6.4 Any deviations from the specified temperature and humidity ranges shall be investigated and documented.

6.5 Corrective actions shall be taken to address any temperature or humidity excursions.

6.6 Temperature and humidity monitoring records shall be maintained for a specified period.

7.0 SAFETY PRECAUTIONS

7.1 All personnel involved in the dispensing of raw materials shall be trained on the potential hazards of the materials and the appropriate safety precautions.

7.2 Appropriate PPE shall be worn at all times during the dispensing process.

7.3 Material Safety Data Sheets (SDS) shall be readily available for all raw materials.

7.4 Spills and leaks shall be cleaned up immediately according to the site's spill control procedures.

7.5 Emergency procedures shall be in place in case of accidents or incidents.

7.6 Housekeeping shall be maintained in the dispensing and storage areas.

7.7 When utilizing mechanical equipment such as stackers (SFT-02) and forklifts (STK-01), operators must be certified and trained in their proper and safe use.

7.8 Ensure proper ventilation is maintained in the dispensing area, especially when handling hazardous materials.

7.9 Follow proper ergonomic practices when lifting and moving heavy containers to prevent injuries.

7.10 Electrical safety checks should be performed regularly on all equipment used in the dispensing area.

8.0 DOCUMENTATION

8.1 The following documents shall be maintained for the dispensing of raw materials:

- Material Request Form
- Dispensing Record
- Certificate of Analysis (COA)
- Weighing Balance Calibration Records
- Temperature and Humidity Monitoring Records
- Equipment Cleaning Log Book
- Line Clearance Checklist

- Deviation Reports (if applicable)
- Training Records for personnel involved in dispensing

8.2 All documents shall be completed accurately and legibly.

8.3 All documents shall be reviewed and approved by the appropriate personnel.

8.4 All documents shall be stored securely and retained for a specified period as per the site's document retention policy.

8.5 All records must comply with ALCOA principles (Attributable, Legible, Contemporaneous, Original, Accurate).

8.6 Any corrections made to records must be initialed and dated, with a brief explanation of the correction.

9.0 TRAINING

9.1 All personnel involved in dispensing of raw material shall be adequately trained.

9.2 The training program shall cover the following topics:

- GMP requirements for dispensing
- This SOP and its requirements
- Material Safety Data Sheets (SDS) review
- Proper use of dispensing equipment
- Weighing techniques
- Line Clearance procedures
- Safety precautions
- Documentation requirements

9.3 Training records shall be maintained for all personnel.

9.4 Periodic retraining shall be conducted to ensure that personnel remain competent in their duties.

10.0 DEVIATIONS

10.1 Any deviation from this SOP shall be documented in a deviation report.

10.2 The deviation report shall include the following information:

- Date and time of the deviation
- Description of the deviation
- Reason for the deviation
- Impact of the deviation
- Corrective actions taken
- Preventive actions implemented

10.3 The deviation report shall be reviewed and approved by the QA Manager.

11.0 AUDIT AND REVIEW

11.1 This SOP shall be audited periodically to ensure compliance with GMP regulations and this SOP.

11.2 This SOP shall be reviewed annually or as needed to ensure it remains current and accurate.

11.3 The review shall be conducted by the QA Manager.

11.4 Any revisions to this SOP shall be approved by the QA Manager.

12.0 ANNEXURES

12.1 Material Request Form Template

12.2 Dispensing Record Template

12.3 Line Clearance Checklist Template

12.4 Training Record Template

13.0 DISTRIBUTION LIST

13.1 Head of Materials Management

13.2 Warehouse Supervisor

13.3 QC Inspector

13.4 Production Supervisor

13.5 QA Manager

Document Approval

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

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