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Company:	NovaThera Pharmaceuticals Pvt. Ltd.	Effective Date:	2025-01-01
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Control of Printed Packaging Materials

Category: Materials Management

Standard Operating Procedure (SOP)

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1.0 PURPOSE

1.1 This Standard Operating Procedure (SOP) defines the procedures for the receipt, storage, dispensing, issuance, handling, and control of printed packaging materials (PPM) at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India to ensure compliance with current Good Manufacturing Practices (cGMP) and regulatory requirements. This SOP covers all printed packaging materials including labels, cartons, leaflets, and tertiary packaging materials.

2.0 SCOPE

2.1 This SOP applies to all personnel involved in the receipt, storage, dispensing, issuance, handling, and control of printed packaging materials within the Materials Management Department and related departments, including Quality Control and Production. This SOP covers all areas where printed packaging materials are stored, handled, or used.

3.0 RESPONSIBILITIES

3.1 Warehouse Operator: Responsible for the receipt, storage, dispensing, issuance, handling, and proper documentation of printed packaging materials as per this SOP.

3.2 QC Inspector: Responsible for the inspection, sampling, and approval/rejection of printed packaging materials as per approved specifications and procedures.

3.3 Production Supervisor: Responsible for the proper use of printed packaging materials in the packaging process and for ensuring line clearance procedures are followed.

3.4 QA Manager: Responsible for overseeing the implementation of this SOP, ensuring compliance with GMP requirements, and approving any deviations or changes to this SOP. Responsible for review and approval of this SOP.

3.5 Head of QA: Responsible for final approval of this SOP and any revisions.

4.0 DEFINITIONS

4.1 Printed Packaging Materials (PPM): All packaging materials bearing printed information, including labels, cartons, leaflets, and tertiary packaging materials.

4.2 Dispensing: The process of issuing the required quantity of printed packaging materials for a specific production batch.

4.3 Line Clearance: The documented process of removing all materials from a packaging line after the completion of a batch to prevent mix-ups.

4.4 FIFO: First-In, First-Out. An inventory management method where the oldest materials are used first.

4.5 FEFO: First-Expiry, First-Out. An inventory management method where materials with the earliest expiry date are used first.

4.6 Quarantine Area: A designated area for holding materials that are pending QC approval.

4.7 Approved Area: A designated area for storing materials that have been released by QC for use.

4.8 Rejected Area: A designated area for storing materials that have been rejected by QC.

4.9 Batch Number: A unique identifier assigned to a specific batch of product.

4.10 Material Code: A unique identifier assigned to each specific printed packaging material.

5.0 PROCEDURE

5.1 Receipt of Printed Packaging Materials

5.1.1 Upon arrival of a shipment of printed packaging materials, the Warehouse Operator shall verify the delivery against the purchase order (PO) and packing slip.

5.1.2 The Warehouse Operator shall record the following information in the Goods Receipt Note (GRN):

- Date of Receipt
- Supplier Name

- Purchase Order Number
- Material Code
- Material Description
- Quantity Received
- Batch Number (if applicable)
- Any visible damage or discrepancies

5.1.3 The Warehouse Operator shall immediately notify the QC Inspector of the receipt of the materials.

5.1.4 The Warehouse Operator shall assign a unique Goods Receipt Note (GRN) number and affix a quarantine label ("Under Quarantine") to the consignment.

5.1.5 The consignment shall be moved to the designated Quarantine Area (Location: QTN-01) using a pallet jack (PJ-01).

5.2 Inspection and Approval/Rejection

5.2.1 The QC Inspector shall collect a representative sample of the printed packaging materials according to the approved sampling plan (QP-QC-005).

5.2.2 The QC Inspector shall perform the following checks:

- Verify the material code, description, and batch number (if applicable) against the PO and specifications.
- Verify the quantity received against the PO and packing slip.
- Inspect the materials for any damage, defects, or discrepancies.
- Inspect the print quality, including font size, color, and legibility.
- Verify the accuracy of the printed information, including the product name, strength, dosage form, expiry date, and any other relevant information.
- Examine the packaging material for proper construction and sealing.

5.2.3 The QC Inspector shall document the inspection results in the QC Inspection Report.

5.2.4 If the printed packaging materials meet all specifications, the QC Inspector shall approve the materials and assign a release number. The QC Inspector shall update the status in the inventory management system. The status shall be changed from “Quarantine” to “Approved”.

5.2.5 If the printed packaging materials do not meet specifications, the QC Inspector shall reject the materials and assign a rejection number. The QC Inspector shall update the status in the inventory management system. The status shall be changed from “Quarantine” to “Rejected”.

5.2.6 The QC Inspector shall affix a "Approved" or "Rejected" label, as applicable, to the consignment.

5.2.7 Approved materials shall be moved to the designated Approved Area (Location: APV-01, APV-02, APV-03) using a forklift (FKL-01, FKL-02). Rejected materials shall be moved to the designated Rejected Area (Location: REJ-01) using a pallet jack (PJ-02).

5.2.8 The QC Inspector shall maintain records of all inspections and approvals/rejections.

5.3 Storage of Printed Packaging Materials

5.3.1 Approved printed packaging materials shall be stored in the designated Approved Area.

5.3.2 The storage area shall be clean, dry, and well-ventilated.

5.3.3 The temperature and humidity in the storage area shall be monitored daily using calibrated temperature and humidity monitoring devices (THM-01, THM-02). Records shall be maintained as per SOP-MM-001 (Environmental Monitoring). Temperature should be maintained between 15°C and 25°C, and relative humidity should be maintained below 65%.

5.3.4 Printed packaging materials shall be stored in a manner that prevents damage, contamination, or deterioration.

5.3.5 Labels and other sensitive materials shall be stored in closed containers or wrapped in protective materials.

5.3.6 Pallets should be stacked in such a manner that it should not block the fire hydrant points.

5.3.7 Storage shall follow FIFO/FEFO principles. The Warehouse Operator shall arrange the materials in the storage area such that the materials with the earliest expiry date or the oldest receipt date are readily accessible.

5.3.8 The Warehouse Operator shall conduct regular stock checks to verify inventory levels and identify any discrepancies. Stock checks shall be performed monthly.

5.3.9 Damaged or expired materials shall be removed from the storage area and disposed of according to SOP-MM-002 (Waste Management).

5.3.10 Periodic cleaning of the storage area should be carried out as per SOP-MM-005 (Cleaning Schedule and Procedure for Warehouse). Cleaning should be performed weekly.

5.4 Dispensing of Printed Packaging Materials

5.4.1 Upon receipt of a dispensing request from the Production Supervisor, the Warehouse Operator shall verify the request against the approved Batch Manufacturing Record (BMR).

5.4.2 The Warehouse Operator shall select the appropriate printed packaging materials based on the material code, description, and batch

number (if applicable).

5.4.3 The Warehouse Operator shall dispense the required quantity of printed packaging materials, ensuring accuracy. The materials shall be dispensed in the dispensing booth (Booth No: DPB-01) to prevent any contamination.

5.4.4 The Warehouse Operator shall record the following information in the dispensing log:

- Date of Dispensing
- Batch Number
- Material Code
- Material Description
- Quantity Dispensed
- Dispensing Request Number
- Warehouse Operator's Signature

5.4.5 The Warehouse Operator and the Production Supervisor shall verify the dispensed materials and quantities independently.

5.4.6 The dispensed materials shall be placed in a sealed container or bag with a label indicating the material code, description, quantity, batch number, and date of dispensing.

5.4.7 The dispensed materials shall be transported to the packaging line by the Warehouse Operator or designated personnel.

5.5 Issuance of Printed Packaging Materials to the Packaging Line

5.5.1 The Production Supervisor shall receive the dispensed printed packaging materials at the packaging line.

5.5.2 The Production Supervisor shall verify the material code, description, quantity, and batch number against the dispensing log.

5.5.3 The Production Supervisor shall store the printed packaging materials in a designated area at the packaging line, protected from damage and contamination.

5.5.4 The packaging line shall be cleared of all materials from the previous batch before starting a new batch. This line clearance activity shall be performed as per SOP-PR-003 (Line Clearance Procedure).

5.5.5 The line clearance shall be verified and documented by the Production Supervisor and a second operator.

5.6 Handling and Use of Printed Packaging Materials on the Packaging Line

5.6.1 The Production Operator shall use the printed packaging materials according to the approved BMR and packaging instructions.

5.6.2 The Production Operator shall ensure that the correct printed packaging materials are used for the correct product and batch.

5.6.3 Any unused printed packaging materials shall be returned to the Warehouse Operator at the end of the packaging run.

5.6.4 The Production Supervisor shall reconcile the quantity of printed packaging materials issued, used, and returned.

5.6.5 Any discrepancies shall be investigated and documented.

5.6.6 Damaged or defective printed packaging materials shall be segregated and disposed of according to SOP-MM-002 (Waste Management).

5.7 Return of Unused Printed Packaging Materials

5.7.1 The Production Supervisor shall return any unused printed packaging materials to the Warehouse Operator along with a reconciliation report.

5.7.2 The Warehouse Operator shall verify the returned materials against the dispensing log and reconciliation report.

5.7.3 The Warehouse Operator shall record the returned quantity in the dispensing log.

5.7.4 The Warehouse Operator shall assess the condition of the returned materials. Materials in good condition may be returned to stock. Materials that are damaged or contaminated shall be disposed of according to SOP-MM-002 (Waste Management).

5.7.5 Returned materials to stock must be accompanied by a signed statement from QA Manager stating that the packaging materials have been examined and is acceptable for return to stock.

5.7.6 The Warehouse Operator shall update the inventory management system to reflect the return of unused materials.

5.8 Destruction of Rejected or Obsolete Printed Packaging Materials

5.8.1 Rejected or obsolete printed packaging materials shall be destroyed to prevent unauthorized use.

5.8.2 The destruction process shall be performed by authorized personnel and witnessed by a second operator.

5.8.3 The destruction process shall be documented in a destruction log, including the following information:

- Date of Destruction
- Material Code
- Material Description
- Quantity Destroyed
- Reason for Destruction
- Method of Destruction
- Signatures of the personnel performing and witnessing the destruction.

5.8.4 The destruction shall be performed in a secure area to prevent any environmental contamination.

5.8.5 The destroyed materials shall be disposed of according to SOP-MM-002 (Waste Management) and local regulations.

6.0 DOCUMENTATION

6.1 The following records shall be maintained:

- Goods Receipt Notes (GRNs)
- QC Inspection Reports
- Dispensing Logs
- Reconciliation Reports
- Destruction Logs
- Temperature and Humidity Monitoring Records
- Cleaning Records
- Inventory Records

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

6.3 All records shall be stored in a secure location and retained for a minimum of five years after the expiry date of the product or as required by local regulations, whichever is longer.

6.4 Electronic records shall be backed up regularly.

7.0 SAFETY PRECAUTIONS

7.1 Personnel handling printed packaging materials shall wear appropriate personal protective equipment (PPE), including safety glasses, gloves, and safety shoes.

7.2 Materials shall be handled in a manner that prevents damage or injury.

7.3 Forklifts (FKL-01, FKL-02), pallet jacks (PJ-01, PJ-02), and stackers (STK-01) shall be operated by trained and authorized personnel only.

7.4 All equipment shall be maintained in good working order.

7.5 The work area shall be kept clean and free of obstructions.

7.6 Emergency procedures shall be in place in case of spills or accidents.

8.0 TRAINING

8.1 All personnel involved in the receipt, storage, dispensing, issuance, handling, and control of printed packaging materials shall be trained on this SOP.

8.2 Training shall be documented, and records shall be maintained.

8.3 Retraining shall be conducted periodically or when there are changes to the SOP.

9.0 ANNEXURES

9.1 Annexure 1: Goods Receipt Note (GRN) Template

9.2 Annexure 2: QC Inspection Report Template

9.3 Annexure 3: Dispensing Log Template

9.4 Annexure 4: Reconciliation Report Template

9.5 Annexure 5: Destruction Log Template

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):			
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