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Title:	Control and Reconciliation of Printed Labels and Cartons	**Version:**	1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
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Control and Reconciliation of Printed Labels and Cartons

Category: Packaging

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Packaging

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1.0 PURPOSE

This procedure defines the controls for receipt, storage, issuance, use, and reconciliation of printed labels and cartons within NovaThera Pharmaceuticals' packaging operations, ensuring correct labeling and preventing mix-ups in pharmaceutical manufacturing. This SOP ensures compliance with current Good Manufacturing Practices (cGMP) and regulatory requirements, minimizing the risk of errors in product identification and traceability.

2.0 SCOPE

This SOP applies to all printed labels and cartons used in the packaging of pharmaceutical products manufactured at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India. This includes labels and cartons for primary packaging (e.g., vials, blister packs), secondary packaging (e.g., cartons), and any other printed material used to identify and track products throughout the packaging process. This SOP excludes pre-printed packaging materials received with the active pharmaceutical ingredient (API). This procedure is applicable to all batches of all pharmaceutical products packaged at NovaThera Pharmaceuticals.

3.0 RESPONSIBILITY

QC Inspector:

- Verifies the receipt of printed labels and cartons against the purchase order and Certificate of Analysis (CoA).
- Performs visual inspection of labels and cartons for defects, accuracy, and conformance to approved specifications.
- Documents inspection results and releases labels and cartons for use.
- Performs line clearance checks before and after packaging operations.
- Reconciles issued and used labels and cartons, and documents discrepancies.
- Samples and retains reserve samples as per established sampling plan.

Production Supervisor:

- Requests labels and cartons from the designated storage area.
- Ensures that labels and cartons are issued to the correct packaging line and for the correct product and batch.
- Supervises the packaging operation to ensure adherence to this SOP.
- Reports any discrepancies in label and carton quantities or defects to the QC Inspector and QA Manager.
- Ensures proper disposal of excess or rejected labels and cartons.
- Trains packaging personnel on the requirements of this SOP.

QA Manager:

- Reviews and approves this SOP and any revisions.
- Oversees the implementation of this SOP and ensures compliance with cGMP requirements.
- Investigates any discrepancies in label and carton reconciliation and implements corrective and preventive actions (CAPA).
- Conducts periodic audits of the label and carton control system.
- Ensures that all personnel involved in label and carton control are adequately trained.

Head of QA:

- Provides final approval for this SOP and any revisions.
- Ensures that the label and carton control system is effective and meets regulatory requirements.
- Provides overall direction and oversight for the quality assurance function.
- Resolves any escalated issues related to label and carton control.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses
- Gloves (nitrile or equivalent)
- Lab coats

Equipment:

- Calibrated weighing scale (SCL-01)
- Calibrated measuring tape (MSR-02)
- Magnifying glass
- Light box
- Barcode scanner (BCS-01)

Documentation:

- Purchase Order
- Certificate of Analysis (CoA)
- Label and Carton Specification Sheet
- Label and Carton Issuance Log
- Label and Carton Reconciliation Form (Form No. NT-PKG-003-01)
- Defective Material Report (Form No. NT-QA-002-01)
- Batch Packaging Record
- Line Clearance Checklist (Form No. NT-PKG-003-02)
- Label and Carton Destruction Log (Form No. NT-QA-002-02)

5.0 PROCEDURE

5.1 Receipt and Inspection of Labels and Cartons

5.1.1 Upon receipt of a shipment of printed labels and cartons, the QC Inspector shall verify the shipment against the purchase order to confirm the correct quantity, product name, and other relevant details.

5.1.2 The QC Inspector shall visually inspect the labels and cartons for any signs of damage, such as tears, creases, or water damage.

5.1.3 The QC Inspector shall compare the received labels and cartons against the approved Label and Carton Specification Sheet to ensure that

they conform to the approved specifications. This includes verification of:

- Product name
- Strength
- Dosage form
- Batch number field
- Expiry date field
- Storage conditions
- Barcode
- Company logo
- Other required information as specified in the specification sheet.

5.1.4 The QC Inspector shall use a calibrated weighing scale (SCL-01) to verify the quantity of labels and cartons received by weight, if applicable, based on established weight per unit standards.

5.1.5 The QC Inspector shall use a calibrated measuring tape (MSR-02) to verify the dimensions of the labels and cartons, if applicable, based on the Label and Carton Specification Sheet.

5.1.6 The QC Inspector shall use a magnifying glass and a light box to inspect the print quality of the labels and cartons, ensuring that the text is clear, legible, and free from defects such as smudging or blurring.

5.1.7 The QC Inspector shall use a barcode scanner (BCS-01) to verify the accuracy of the barcode on the labels and cartons, ensuring that it matches the product code and other relevant information.

5.1.8 The QC Inspector shall record the results of the inspection in the Label and Carton Issuance Log, noting any discrepancies or defects.

5.1.9 If any discrepancies or defects are found, the QC Inspector shall quarantine the affected labels and cartons and notify the QA Manager. A Defective Material Report (Form No. NT-QA-002-01) shall be initiated.

5.1.10 If the labels and cartons meet the approved specifications, the QC Inspector shall release them for use and record the release in the Label and Carton Issuance Log. The released labels and cartons shall be moved to the designated storage area.

5.1.11 The QC Inspector shall sample and retain reserve samples of each lot of labels and cartons, as per the established sampling plan. These reserve samples shall be stored under appropriate conditions for the duration of the product's shelf life, plus one year.

5.2 Storage of Labels and Cartons

5.2.1 Labels and cartons shall be stored in a secure, limited-access storage area that is protected from unauthorized access, environmental conditions (e.g., excessive heat, humidity, light), and pests.

5.2.2 The storage area shall be organized and clearly labeled to prevent mix-ups. Labels and cartons shall be stored in a manner that prevents damage.

5.2.3 Access to the label and carton storage area shall be restricted to authorized personnel only.

5.2.4 The storage area shall be regularly inspected for cleanliness, pest control, and proper environmental conditions.

5.2.5 Labels and cartons shall be stored in their original packaging or in suitable containers that protect them from damage.

5.2.6 Labels and cartons shall be segregated by product, strength, and batch number to prevent mix-ups.

5.2.7 Expired or obsolete labels and cartons shall be removed from the storage area and disposed of in accordance with SOP-QA-005, "Waste Management."

5.3 Issuance of Labels and Cartons

5.3.1 The Production Supervisor shall request labels and cartons from the designated storage area using the Label and Carton Issuance Log. The request shall specify the product name, strength, batch number, quantity required, and the packaging line for which the labels and cartons are needed.

5.3.2 The QC Inspector shall verify the request against the Batch Packaging Record to ensure that the correct labels and cartons are being issued.

5.3.3 The QC Inspector shall issue the requested quantity of labels and cartons to the Production Supervisor, recording the issuance in the Label and Carton Issuance Log.

5.3.4 The Production Supervisor shall acknowledge receipt of the labels and cartons in the Label and Carton Issuance Log.

5.3.5 The issued labels and cartons shall be transported to the packaging line in a secure manner to prevent damage or loss.

5.4 Use of Labels and Cartons on the Packaging Line

5.4.1 Before starting the packaging operation, the QC Inspector shall perform a line clearance check to ensure that the packaging line is free from any labels, cartons, or other materials from previous packaging operations. The line clearance check shall be documented on the Line Clearance Checklist (Form No. NT-PKG-003-02).

5.4.2 The Production Supervisor shall ensure that the correct labels and cartons are loaded onto the packaging equipment.

5.4.3 The Production Supervisor shall visually inspect the labels and cartons during the packaging operation to ensure that they are being applied correctly and that there are no defects.

5.4.4 The QC Inspector shall periodically monitor the packaging operation to ensure that the labels and cartons are being used correctly and that the packaging process is in compliance with cGMP requirements.

5.4.5 Any unused or rejected labels and cartons shall be collected and returned to the QC Inspector for reconciliation.

5.5 Reconciliation of Labels and Cartons

5.5.1 At the end of the packaging operation, the Production Supervisor shall collect all unused and rejected labels and cartons and return them to the QC Inspector.

5.5.2 The QC Inspector shall reconcile the issued labels and cartons against the number of products packaged and the number of unused and rejected labels and cartons. The reconciliation shall be documented on the Label and Carton Reconciliation Form (Form No. NT-PKG-003-01).

5.5.3 Any discrepancies in the reconciliation shall be investigated by the QA Manager. The investigation shall be documented, and corrective and preventive actions (CAPA) shall be implemented to prevent recurrence.

5.5.4 The Label and Carton Reconciliation Form (Form No. NT-PKG-003-01) shall be reviewed and approved by the QA Manager.

5.6 Disposal of Rejected and Unused Labels and Cartons

5.6.1 Rejected labels and cartons, and any unused labels and cartons after reconciliation, shall be rendered unusable to prevent unauthorized use. This may involve shredding, incineration, or other appropriate methods.

5.6.2 The destruction of rejected and unused labels and cartons shall be witnessed by the QC Inspector and another authorized person.

5.6.3 The destruction shall be documented in the Label and Carton Destruction Log (Form No. NT-QA-002-02), including the date of destruction, the quantity destroyed, the method of destruction, and the signatures of the witnesses.

6.0 POST-PACKAGING ACTIVITIES

6.1 The QC Inspector shall conduct a final line clearance to ensure all labels and cartons pertaining to the specific batch are removed from the packaging area.

6.2 The Production Supervisor shall ensure that all documentation related to the packaging operation is completed and submitted to the QA department for review.

6.3 The QA Manager shall review the Batch Packaging Record, including the Label and Carton Reconciliation Form, to ensure that all documentation is complete and accurate.

7.0 SAFETY PRECAUTIONS

7.1 Personnel handling labels and cartons shall wear appropriate PPE, including safety glasses and gloves.

7.2 Personnel shall be trained on the safe handling of packaging materials.

7.3 Labels and cartons shall be stored in a manner that prevents them from falling or causing other hazards.

7.4 Care should be taken when handling sharp objects such as knives or scissors, if used to open packaging.

7.5 Any spills or leaks of packaging materials shall be cleaned up immediately.

7.6 Damaged or defective labels and cartons shall be handled with care to avoid injury.

7.7 Material Safety Data Sheets (MSDS) for any chemicals used in the packaging process shall be readily available.

8.0 APPROVALS

Prepared By: Production Supervisor

Reviewed By: QA Manager

Approved By: Head of QA

Date: [Leave blank for manual completion]

Controlled Document Notice

Document Approval

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

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