Document Type:	Standard Operating Procedure (SOP)	**SOP Code:**	SOP-PKG-004
Title:	In-Process Quality Control (IPQC) Checks for Packaging	**Version:**	1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
Location:	Pune, India	**Review Date:**	2026-01-01

In-Process Quality Control (IPQC) Checks for Packaging

Category: Packaging

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Quality Control

Title: In-Process Quality Control (IPQC) Checks for Packaging

SOP No.: SOP-PKG-004

Version No.: 1.0

Effective Date: 2025-01-01

1.0 PURPOSE

This procedure defines the standardized methodology for performing In-Process Quality Control (IPQC) checks during the packaging of pharmaceutical products at NovaThera Pharmaceuticals, ensuring adherence to Good Manufacturing Practices (GMP) and maintaining product quality throughout the packaging process in pharmaceutical manufacturing.

2.0 SCOPE

This SOP applies to all personnel involved in the packaging of pharmaceutical products at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India. It covers all stages of the packaging process, from the receipt of packaging materials to the completion of the final packaged product, for all products manufactured and packaged at the facility. This procedure excludes the initial release testing of raw packaging materials, which is covered under a separate SOP.

3.0 RESPONSIBILITY

QC Inspector:

- Performs IPQC checks according to this SOP.
- Documents all IPQC results accurately and legibly on the approved forms.
- Notifies the Production Supervisor and QA Manager immediately of any deviations from established specifications or procedures.
- Ensures that rejected materials or products are clearly identified and segregated.
- Maintains a clean and organized work area.

Production Supervisor:

- Ensures that all packaging activities are performed in accordance with this SOP and other relevant procedures.
- Provides adequate training and supervision to packaging personnel.
- Investigates any deviations or out-of-specification results identified during IPQC checks.
- Implements corrective and preventive actions (CAPA) as necessary to address any issues identified.
- Ensures that all equipment is properly calibrated and maintained.

QA Manager:

- Reviews and approves this SOP and any revisions thereto.
- Provides oversight of the IPQC program to ensure compliance with GMP requirements.
- Reviews and approves investigation reports for deviations or out-of-specification results.
- Ensures that appropriate CAPA measures are implemented and effective.
- Conducts periodic audits of the packaging process to identify areas for improvement.

Head of QA:

- Provides final approval for this SOP and any revisions.
- Oversees the overall quality assurance program at NovaThera Pharmaceuticals.
- Ensures compliance with all applicable regulatory requirements.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses
- Gloves (nitrile or latex, as appropriate for the product being packaged)
- Hairnet
- Mask (as required for the product being packaged)
- Lab coat or gown

Equipment:

- Calibrated weighing balance (BAL-01)

- Calibrated measuring tape/ruler (MEA-03)
- Calipers (CAL-02)
- Visual inspection station with appropriate lighting (VIS-01)
- Magnifying glass (MAG-01)
- Defect reference samples (DRS-PKG-01)
- Torque meter (TRQ-01) (if applicable, for closure testing)
- Sealing Machine (SLM-01)
- Blister Packing Machine (BPM-01)(If applicable)
- Strip packing Machine (SPM-01)(If applicable)
- Cartoning Machine (CTM-01)(If applicable)

Documentation:

- Packaging Batch Record (PBR-PKG-001)
- In-Process Quality Control Checklist (IPQC-PKG-001)
- Deviation Report Form (DRF-001)
- Equipment Calibration Logbook (ECL-001)
- Training Record (TR-001)

5.0 PROCEDURE

5.1 Line Clearance

5.1.1 Before the commencement of any packaging operation, the Production Supervisor or designated trained personnel will perform a thorough line clearance.

5.1.2 The Production Supervisor verifies that the packaging line is free from any materials, documents, or products from previous operations.

5.1.3 The Production Supervisor inspects the packaging area, including all equipment, surfaces, and surrounding areas.

5.1.4 The Production Supervisor removes any obsolete labels, packaging materials, or waste from the area.

5.1.5 The Production Supervisor verifies that the correct product, packaging materials, and labeling are present for the current packaging order, as indicated on the Packaging Batch Record (PBR-PKG-001).

5.1.6 The Production Supervisor ensures that the area is clean and free from any potential contaminants.

5.1.7 The Production Supervisor documents the line clearance in the Packaging Batch Record (PBR-PKG-001), including the date, time, and signature.

5.1.8 The QC Inspector verifies the line clearance performed by the Production Supervisor.

5.1.9 The QC Inspector independently inspects the packaging line, equipment, and materials.

5.1.10 The QC Inspector confirms that the line clearance has been performed adequately and that all requirements have been met.

5.1.11 The QC Inspector documents the verification in the Packaging Batch Record (PBR-PKG-001), including the date, time, and signature. If applicable, attaches the line clearance checklist.

5.1.12 Only after the Production Supervisor and QC Inspector have verified the line clearance can the packaging operation commence.

5.2 Receipt of Packaging Materials

5.2.1 The QC Inspector verifies that all packaging materials received at the packaging line match the specifications listed in the Packaging Batch Record (PBR-PKG-001).

5.2.2 The QC Inspector checks the packaging materials for any visible damage, defects, or contamination.

5.2.3 The QC Inspector verifies the quantity of packaging materials received against the quantity specified in the Packaging Batch Record (PBR-PKG-001).

5.2.4 The QC Inspector ensures that the packaging materials are properly stored and protected from damage or contamination.

5.2.5 The QC Inspector samples the packaging materials according to the sampling plan outlined in the relevant SOP.

5.2.6 The QC Inspector performs identification tests on the packaging materials to verify their authenticity.

5.2.7 The QC Inspector documents all observations and test results in the In-Process Quality Control Checklist (IPQC-PKG-001).

5.2.8 If any discrepancies or issues are identified, the QC Inspector notifies the Production Supervisor and QA Manager immediately.

5.2.9 The QA Manager investigates the issue and determines the appropriate course of action.

5.3 Inspection of Primary Packaging Components (Bottles, Blisters, Strips etc)

5.3.1 The QC Inspector visually inspects primary packaging components (e.g., bottles, blisters, strips) for defects such as cracks, chips, dents, or discoloration using the visual inspection station (VIS-01).

5.3.2 The QC Inspector measures critical dimensions of the primary packaging components using calibrated calipers (CAL-02) to ensure they meet specifications. Dimensions can include length, width, diameter, and height as per requirement.

5.3.3 The QC Inspector performs a weight check on a sample of the primary packaging components using the calibrated weighing balance (BAL-01) to ensure consistency.

5.3.4 The QC Inspector verifies the integrity of seals (if applicable) on primary packaging components.

5.3.5 The QC Inspector compares the primary packaging components to defect reference samples (DRS-PKG-01) to identify any unacceptable defects.

5.3.6 The QC Inspector records all inspection results in the In-Process Quality Control Checklist (IPQC-PKG-001).

5.3.7 If any defects or non-conformances are identified, the QC Inspector segregates the affected components and notifies the Production Supervisor and QA Manager.

5.4 Label Inspection

5.4.1 The QC Inspector verifies that the correct labels are being used for the product being packaged, as specified in the Packaging Batch Record (PBR-PKG-001).

5.4.2 The QC Inspector inspects the labels for any printing errors, such as misspellings, incorrect font sizes, or missing information.

5.4.3 The QC Inspector verifies that the labels contain all required information, including the product name, strength, dosage form, lot number, expiry date, and any required warnings or precautions.

5.4.4 The QC Inspector inspects the labels for proper adhesion and ensures that they are securely affixed to the packaging containers.

5.4.5 The QC Inspector verifies that the labels are clean and free from any smudges, tears, or other damage.

5.4.6 The QC Inspector compares the labels to approved label artwork to ensure accuracy.

5.4.7 The QC Inspector documents all inspection results in the In-Process Quality Control Checklist (IPQC-PKG-001).

5.4.8 If any discrepancies or issues are identified, the QC Inspector notifies the Production Supervisor and QA Manager immediately.

5.5 Filled Container Checks (Weight/Count)

5.5.1 The QC Inspector verifies the fill weight/count of product in the filled containers using a calibrated weighing balance (BAL-01) or by manual counting as per the Packaging Batch Record (PBR-PKG-001).

5.5.2 The QC Inspector selects a predetermined number of filled containers at regular intervals (e.g., every 15 minutes or every 500 containers) for weight/count verification. The frequency should be defined in the PBR-PKG-001.

5.5.3 The QC Inspector compares the weight/count of the filled containers to the target weight/count specified in the Packaging Batch Record (PBR-PKG-001).

5.5.4 The QC Inspector calculates the average weight/count and the standard deviation to ensure that the filling process is consistent and within acceptable limits.

5.5.5 The QC Inspector documents all weight/count measurements and calculations in the In-Process Quality Control Checklist (IPQC-PKG-001).

5.5.6 If any filled containers are found to be outside of the acceptable weight/count limits, the QC Inspector immediately stops the filling process and notifies the Production Supervisor.

5.6 Sealing and Closure Integrity (If Applicable)

5.6.1 For sealed containers, the QC Inspector visually inspects the seals for any defects, such as incomplete seals, leaks, or damage.

5.6.2 The QC Inspector performs a seal strength test, if applicable, to ensure that the seals meet the required strength specifications.

5.6.3 For containers with closures (e.g., bottles with caps), the QC Inspector verifies that the closures are properly tightened and that they provide an adequate seal using a calibrated torque meter (TRQ-01).

5.6.4 The QC Inspector performs a leak test on a sample of sealed containers to ensure that they are leak-proof.

5.6.5 The QC Inspector documents all inspection results in the In-Process Quality Control Checklist (IPQC-PKG-001).

5.6.6 If any sealing or closure integrity issues are identified, the QC Inspector notifies the Production Supervisor and QA Manager immediately.

5.7 Verification of Printed Information on Packaging

5.7.1 The QC Inspector verifies that all printed information on the packaging, such as lot numbers, expiry dates, and barcodes, is correct and legible.

5.7.2 The QC Inspector compares the printed information to the information specified in the Packaging Batch Record (PBR-PKG-001) and approved label artwork.

5.7.3 The QC Inspector uses a barcode scanner (if applicable) to verify that the barcodes are scanning correctly and that they contain the correct information.

5.7.4 The QC Inspector documents all verification results in the In-Process Quality Control Checklist (IPQC-PKG-001).

5.7.5 If any discrepancies or errors are identified, the QC Inspector notifies the Production Supervisor and QA Manager immediately.

5.8 Carton Inspection (If Applicable)

5.8.1 The QC Inspector verifies the cartons for any physical damage such as dents, tears or scratches.

5.8.2 The QC Inspector verifies that the printed information on the cartons, such as product name, strength, lot number and expiry date, is correct and legible.

5.8.3 The QC Inspector also verifies that the printed information is complying with the approved artwork.

5.8.4 The QC Inspector ensures that the cartons are properly sealed and secured using appropriate sealing materials.

5.8.5 The QC Inspector ensures that the carton weight is withing the prescribed limits.

6.0 POST-PACKAGING ACTIVITIES

6.1 The Production Supervisor ensures that all completed packaged products are properly stored in a designated quarantine area awaiting final release by Quality Assurance.

6.2 The Production Supervisor reconciles all packaging materials, including labels, cartons, and inserts, to account for all materials used and any unused materials.

6.3 The Production Supervisor documents the reconciliation results in the Packaging Batch Record (PBR-PKG-001).

6.4 The QC Inspector reviews the Packaging Batch Record (PBR-PKG-001) and all associated documentation, including the In-Process Quality Control Checklist (IPQC-PKG-001), to ensure that all IPQC checks have been performed and that all results are within acceptable limits.

6.5 The QA Manager reviews the Packaging Batch Record (PBR-PKG-001) and all associated documentation to ensure that all requirements have been met and that the packaging process has been performed in accordance with GMP guidelines.

6.6 The Head of QA approves the release of the packaged product after reviewing all documentation and ensuring that all quality requirements have been met.

6.7 All rejected packaging materials and filled containers shall be disposed off as per the SOP on Waste Management.

7.0 SAFETY PRECAUTIONS

7.1 All personnel involved in the packaging process must wear appropriate PPE, including safety glasses, gloves, hairnets, and masks, as required.

7.2 All equipment must be operated in accordance with the manufacturer's instructions.

7.3 Personnel must be trained on the proper handling of packaging materials and filled containers to prevent injury.

7.4 All work areas must be kept clean and free from hazards.

7.5 Any spills or leaks must be cleaned up immediately.

7.6 The use of sharp objects (e.g., knives, scissors) should be minimized and handled with extreme care.

7.7 Ensure proper ventilation in the packaging area to minimize exposure to dust or fumes.

7.8 In case of any accident or injury, report it immediately to the Production Supervisor.

8.0 APPROVALS

Prepared By: QC Inspector

Reviewed By: QA Manager

Approved By: Head of QA

Date: [Leave blank for manual completion]

Document Approval

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

Document Control Information

Document ID: SOP-PKG-004

Version: 1.0

Effective Date: 2025-01-01

Next Review Date: 2026-01-01

Generated by: NovaThera SOP Generator System