

Document Type:	Standard Operating Procedure (SOP)	SOP Code:	SOP-PKG-001
Title:	Primary Packaging Materials Handling	Version:	2.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	Effective Date:	2025-01-01
Location:	Pune, India	Review Date:	2026-01-01

Primary Packaging Materials Handling

Category: Packaging

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd., Pune, India

Department: Packaging

Title: Primary Packaging Materials Handling

SOP No.: SOP-PKG-001

Version No.: 2.0

Effective Date: 2025-07-01

1.0 PURPOSE

This Standard Operating Procedure (SOP) outlines the requirements for the receipt, storage, sampling, testing, and issuance of primary packaging materials at NovaThera Pharmaceuticals for use in pharmaceutical manufacturing. The procedure ensures the quality, safety, and integrity of primary packaging materials, preventing contamination, mix-ups, and deviations from established specifications. This SOP complies with current Good Manufacturing Practices (cGMP) as defined by FDA, ICH Q7, Q9, Q10 and WHO GMP guidelines to ensure products meet defined quality standards and regulatory requirements, contributing to patient safety and product efficacy. The objective is to establish a robust and controlled system for handling primary packaging materials, minimizing risks and ensuring consistent quality throughout the packaging process, based on Quality by Design (QbD) principles.

2.0 SCOPE

This SOP applies to all primary packaging materials used in the packaging of pharmaceutical products manufactured at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India. This includes, but is not limited to, bottles, vials, ampoules, blister packs, closures (e.g., caps, stoppers), labels, cartons, and printed foils. The scope encompasses the entire lifecycle of these materials, from their arrival at the facility through release for use in production. This SOP covers activities performed in the receiving area, quarantine zone, sampling area, quality control laboratory, and packaging material storage areas. This SOP

specifically excludes secondary and tertiary packaging materials (e.g., shipping boxes, pallets), which are addressed in SOP-PKG-002. This SOP adheres to the requirements outlined in 21 CFR Parts 210 and 211, ICH Q7, Q9, Q10, and other applicable regulations pertaining to the receipt, storage, testing, and release of materials used in pharmaceutical manufacturing.

3.0 RESPONSIBILITY

QC Inspector: Responsible for the sampling, inspection, and testing of primary packaging materials in accordance with approved specifications and standard test procedures. This includes visual inspection for defects, dimensional checks using calibrated measuring instruments (MIC-01, CAL-02), and analytical testing using appropriate laboratory equipment (e.g., SPECT-01 for spectrophotometry). The QC Inspector is responsible for ensuring that all testing is performed according to approved methods and that all data is accurately recorded and reported in a timely manner. Performance metrics include timely completion of testing (within 24 hours of sampling), accuracy of test results (target 100%), and adherence to approved SOPs (target 100%).

Production Supervisor: Responsible for ensuring that primary packaging materials are handled, stored, and used in accordance with this SOP. This includes ensuring proper identification, traceability, and segregation of materials. The Production Supervisor is responsible for verifying that all personnel involved in the handling of primary packaging materials are properly trained and qualified. They have the authority to stop production if there are any concerns about the quality or integrity of the packaging materials and must immediately escalate any deviations or anomalies to the QA Manager. They are also responsible for maintaining accurate inventory records of primary packaging materials. They oversee the cleaning and sanitation of packaging areas.

QA Manager: Responsible for overseeing the implementation and maintenance of this SOP. This includes reviewing and approving all documentation related to the receipt, storage, testing, and release of primary packaging materials. The QA Manager is responsible for ensuring that all activities are performed in accordance with cGMP requirements and that any deviations or non-conformances are properly investigated and addressed. The QA Manager has the authority to approve or reject primary packaging materials based on the results of testing and inspection. The QA Manager also ensures that this SOP is reviewed and updated as needed to reflect current regulatory requirements and best practices, as well as implementing change control.

Head of QA: Responsible for the overall quality assurance program at NovaThera Pharmaceuticals. This includes providing strategic direction and oversight for all quality-related activities, including the handling of primary packaging materials. The Head of QA serves as the primary liaison with regulatory agencies (e.g., FDA, EMA) on matters related to quality assurance. The Head of QA is responsible for ensuring that the company's quality system is effective in preventing and detecting quality problems. They ensure adherence to regulatory requirements and provide resources for necessary training and process improvements. They also have final approval on all SOPs and deviations related to primary packaging materials.

4.0 MATERIALS & EQUIPMENT

PPE:

- Safety glasses (ANSI Z87.1 certified)
- Disposable gloves (nitrile, powder-free, meeting ASTM D6319 standards)
- Lab coats (lint-free, 100% cotton or synthetic blend)
- Hair nets or beard covers (as required by area classification)
- Dedicated footwear (cleanroom shoes or overshoes, as required by area classification)
- Dust mask/Respirator (NIOSH approved N95 or higher, if handling dusty materials)

Equipment:

- Calibrated weighing scale (BAL-01, accuracy ± 0.1 g, calibration traceable to NIST)
- Calibrated measuring instruments (MIC-01: calipers, MIC-02: micrometers, calibration traceable to NIST)
- Sampling tools (spatulas, scoops, sterile containers)
- Temperature and humidity monitoring system (TEM-01, accuracy ± 0.5 °C and $\pm 5\%$ RH, calibration traceable to NIST)
- Forklift or pallet jack (FLT-01) – if applicable for handling large quantities of packaging materials
- Light box (LTB-01) – for visual inspection of packaging materials
- Spectrophotometer (SPECT-01) – for color verification
- Tensile Tester (TEN-01) – for material strength testing
- Automated Visual Inspection System (AVI-01) – for automated defect detection, where applicable

Documentation:

- Primary Packaging Material Specifications (PMS-XXX-YY, where XXX is the material code and YY is the version number)
- Material Safety Data Sheets (MSDS) or Safety Data Sheets (SDS)
- Certificate of Analysis (CoA) from the supplier
- Goods Receipt Note (GRN)
- Sampling Plan (SMP-PKG-001)
- Inspection Checklist (INS-PKG-001)
- Testing Protocol (TP-PKG-XXX)
- Release for Use Form (RFU-PKG-001)
- Inventory Log (INV-PKG-001)
- Deviation Report Form (DEV-001)
- Corrective and Preventive Action (CAPA) Form (CAPA-001)

Reagents/Chemicals:

- If applicable: Reagents and standards used for analytical testing should be of analytical grade or higher, with documented traceability.

5.0 PROCEDURE

5.1 Pre-Activity Preparation

- 5.1.1 Verify that the work area is clean, dry, and free from any extraneous materials or debris. Document cleaning on the area's cleaning log (CLN-LOG-PKG).
- 5.1.2 Review the applicable Primary Packaging Material Specification (PMS-XXX-YY) and Certificate of Analysis (CoA) to understand the material requirements and acceptance criteria. Verify the PMS is the latest approved version.
- 5.1.3 Ensure that all necessary equipment (e.g., weighing scale, measuring instruments) is calibrated and in good working order. Check calibration stickers for validity.
- 5.1.4 Don appropriate PPE as specified in Section 4.0.
- 5.1.5 Review the Goods Receipt Note (GRN) for the incoming packaging material to verify the quantity, supplier, and material code.
- 5.1.6 Ensure the receiving area has appropriate temperature and humidity conditions (20-25°C, 40-60% RH). Monitor and record temperature and humidity using TEM-01.
- 5.1.7 Confirm that the material is appropriately labeled with the supplier's name, material code, batch number, and quantity.
- 5.1.8 Access the electronic document management system (EDMS) to retrieve the latest approved versions of all required documents, ensuring data integrity and adherence to ALCOA+ principles.

5.2 Receipt and Quarantine

- 5.2.1 Upon arrival of the primary packaging material, visually inspect the delivery vehicle for any signs of damage or contamination. Record observations on the GRN.
- 5.2.2 Verify the material code, quantity, and batch number against the purchase order and the supplier's packing list. Resolve any discrepancies before proceeding. Document any discrepancies on the GRN and initiate a deviation report (DEV-001) if necessary.
- 5.2.3 Transfer the primary packaging material to the designated quarantine area. Ensure the area is clearly marked and segregated from released materials.
- 5.2.4 Assign a unique quarantine number to the incoming material and record it in the inventory log (INV-PKG-001) along with the date of receipt, material code, batch number, quantity, and supplier name.
- 5.2.5 Affix a "Quarantine" label to each container or pallet of primary packaging material. The label must include the quarantine number, material code, and date of receipt.
- 5.2.6 Record the temperature and humidity of the quarantine area daily. Maintain a temperature between 15-25°C and humidity between 30-65% RH. Any excursions must be investigated and documented as a deviation (DEV-001).
- 5.2.7 Evaluate the supplier's Certificate of Analysis (CoA) for compliance with the NovaThera Pharmaceuticals specifications (PMS-XXX-YY). If the CoA is not available, request it from the supplier before proceeding.

- 5.2.8 Review the CoA against the approved specifications, focusing on critical parameters such as material composition, dimensions, and physical properties. Record the CoA review results in the inventory log (INV-PKG-001).

5.3 Sampling

- 5.3.1 Following the approved sampling plan (SMP-PKG-001), select a representative sample of primary packaging material for testing. The sampling plan should be based on statistical principles and consider the batch size and variability of the material.
- 5.3.2 Perform sampling in a designated sampling area that is clean and environmentally controlled.
- 5.3.3 Use appropriate sampling tools (e.g., spatulas, scoops, sterile containers) that have been cleaned and sanitized. Document the cleaning process in the equipment logbook.
- 5.3.4 Label each sample container with the material code, batch number, quarantine number, date of sampling, and the name of the person who performed the sampling.
- 5.3.5 Record the sampling details in the inventory log (INV-PKG-001) and the sampling log.
- 5.3.6 Transport the samples to the quality control laboratory for testing. Maintain sample integrity during transport.

5.4 In-Process Controls

- 5.4.1 ****Visual Inspection:**** Perform a 100% visual inspection of the packaging materials for any visible defects, such as cracks, scratches, discoloration, or foreign matter. The inspection should be performed under a light box (LTB-01). Acceptance criteria: No more than 0.5% defective units per batch. Record inspection results in the inspection checklist (INS-PKG-001). Any defects exceeding the acceptance criteria must be documented as a deviation (DEV-001).
- 5.4.2 ****Dimensional Checks:**** Using calibrated measuring instruments (MIC-01, MIC-02), verify the dimensions of the packaging materials against the approved specifications (PMS-XXX-YY). Acceptance criteria: Dimensions must be within the specified tolerance limits. Record measurements in the inspection checklist (INS-PKG-001). Any dimensions outside the tolerance limits must be documented as a deviation (DEV-001).
- 5.4.3 ****Material Identification:**** Perform material identification testing using appropriate analytical methods (e.g., spectrophotometry using SPECT-01) to confirm the identity of the packaging material. Acceptance criteria: The material identification test results must match the reference standard. Record the test results in the testing protocol (TP-PKG-XXX). Any discrepancy in material identification must be documented as a deviation (DEV-001).
- 5.4.4 ****Color Verification:**** Verify the color of the packaging material against the approved color standard using a spectrophotometer (SPECT-01). Acceptance criteria: The color difference (ΔE) must be within the specified tolerance limits. Record the color verification results in the testing protocol (TP-PKG-XXX). Any color difference exceeding the tolerance limits must be documented as a deviation (DEV-001).
- 5.4.5 ****Functional Testing:**** Perform functional testing of the packaging materials, such as closure torque testing, leak testing, and seal strength testing, as applicable. Acceptance criteria: The functional test results must meet the specified requirements. Record the functional test results in the testing protocol (TP-PKG-XXX). Any functional test results that do not meet the requirements must

be documented as a deviation (DEV-001).

- 5.4.6 ****Environmental Monitoring:**** Conduct routine environmental monitoring of the packaging material storage areas to ensure that temperature, humidity, and particulate matter levels are within acceptable limits. Acceptance criteria: Temperature 15-25°C, humidity 30-65% RH, particulate matter levels within ISO Class 8 limits. Record the environmental monitoring data in the environmental monitoring log. Any excursions outside the acceptance criteria must be investigated and documented as a deviation (DEV-001).

5.5 Testing and Release

- 5.5.1 Perform all required testing according to the approved testing protocol (TP-PKG-XXX).
- 5.5.2 Record all test results accurately and completely in the testing protocol (TP-PKG-XXX). Ensure that all data is traceable, attributable, contemporaneous, original, and accurate (ALCOA+ principles).
- 5.5.3 Review the test results and the CoA against the approved specifications (PMS-XXX-YY).
- 5.5.4 If the material meets all specifications, prepare a Release for Use Form (RFU-PKG-001) and submit it to the QA Manager for approval.
- 5.5.5 If the material fails to meet any specification, document the failure as a deviation (DEV-001) and initiate an investigation.
- 5.5.6 Upon approval of the Release for Use Form (RFU-PKG-001), remove the "Quarantine" label from the packaging material and affix a "Released" label.
- 5.5.7 Record the release date and the name of the person who performed the release in the inventory log (INV-PKG-001).
- 5.5.8 Move the released packaging material to the designated storage area for released materials. Ensure the area is clearly marked and segregated from quarantined materials.

6.0 POST-ACTIVITY PROCEDURES

- 6.0.1 Ensure that all unused samples are properly disposed of in accordance with the company's waste management procedures. Record the disposal in the waste disposal log.
- 6.0.2 Return all testing equipment to its designated storage location and ensure it is clean and in good working order.
- 6.0.3 Clean and sanitize the sampling area and the quality control laboratory. Document the cleaning process in the area's cleaning log (CLN-LOG-PKG or CLN-LOG-QC).
- 6.0.4 Review all data generated during the receipt, sampling, testing, and release process to ensure accuracy, completeness, and compliance with this SOP and all applicable regulations.
- 6.0.5 Complete all required documentation, including the Goods Receipt Note (GRN), inventory log (INV-PKG-001), sampling log, testing protocol (TP-PKG-XXX), Release for Use Form (RFU-PKG-001), and any deviation reports (DEV-001).
- 6.0.6 Store all records in a secure location in accordance with the company's record retention policy. Maintain both electronic and paper records, ensuring data integrity and traceability.

7.0 SAFETY PRECAUTIONS

- 7.0.1 Always wear appropriate PPE as specified in Section 4.0.
- 7.0.2 Handle primary packaging materials with care to avoid damage or contamination.
- 7.0.3 Use proper lifting techniques when handling heavy containers or pallets.
- 7.0.4 Be aware of potential hazards associated with the handling of specific packaging materials (e.g., sharp edges, dust). Refer to the Material Safety Data Sheet (MSDS) or Safety Data Sheet (SDS) for detailed information.
- 7.0.5 In case of spills or leaks, clean up immediately using appropriate spill control materials. Report any spills or leaks to the Production Supervisor.
- 7.0.6 Follow all safety procedures for the operation of equipment, such as forklifts and pallet jacks.
- 7.0.7 In case of emergency (e.g., fire, chemical exposure), follow the company's emergency response plan. Know the location of emergency exits, fire extinguishers, and first aid kits.
- 7.0.8 Conduct a Job Safety Analysis (JSA) for each task to identify potential hazards and implement appropriate control measures.

8.0 QUALITY CONTROL MEASURES

- 8.0.1 All primary packaging materials must meet the specifications outlined in the Primary Packaging Material Specifications (PMS-XXX-YY).
- 8.0.2 All testing must be performed according to approved testing protocols (TP-PKG-XXX).
- 8.0.3 The sampling plan (SMP-PKG-001) must be based on statistical principles and ensure that a representative sample is taken for testing.
- 8.0.4 Acceptance criteria for all tests must be clearly defined in the testing protocol (TP-PKG-XXX).
- 8.0.5 All data must be accurately recorded and reviewed to ensure compliance with specifications.
- 8.0.6 The QA Manager must approve the Release for Use Form (RFU-PKG-001) before any primary packaging material is released for use in production.
- 8.0.7 Routine audits of the primary packaging material handling process will be conducted to ensure compliance with this SOP and all applicable regulations.
- 8.0.8 Implement a vendor qualification program to ensure that all suppliers of primary packaging materials meet the company's quality standards.
- 8.0.9 Utilize trend analysis to monitor the quality of incoming primary packaging materials and identify any potential issues.

9.0 DOCUMENTATION AND RECORDS

- 9.0.1 All documentation related to the receipt, storage, testing, and release of primary packaging materials must be accurate, complete, and legible.
- 9.0.2 All records must be maintained in a secure location in accordance with the company's record retention policy.
- 9.0.3 Electronic records must be protected from unauthorized access, alteration, or deletion. Implement appropriate security measures, such as passwords and access controls.
- 9.0.4 All entries in paper records must be made in indelible ink and signed and dated by the person making the entry.

- 9.0.5 Corrections to paper records must be made by drawing a single line through the incorrect entry, initialing and dating the correction, and providing a brief explanation for the correction.
- 9.0.6 Electronic records must be backed up regularly to prevent data loss.
- 9.0.7 Maintain an audit trail for all electronic records to track changes and ensure accountability.
- 9.0.8 Store all records for a minimum of [Specify Number] years after the expiration date of the product that was packaged using the primary packaging material.

10.0 DEVIATIONS AND CORRECTIVE ACTIONS

- 10.0.1 Any deviation from this SOP must be documented in a deviation report (DEV-001).
- 10.0.2 The deviation report must include a description of the deviation, the date and time of the deviation, the cause of the deviation, and the corrective action taken to address the deviation.
- 10.0.3 The deviation report must be reviewed and approved by the QA Manager.
- 10.0.4 If the deviation is determined to be significant, a corrective and preventive action (CAPA) plan must be developed to prevent recurrence of the deviation.
- 10.0.5 The CAPA plan must include a timeline for implementation and a method for verifying the effectiveness of the corrective action.
- 10.0.6 All CAPAs must be tracked and closed out in a timely manner.

11.0 TRAINING REQUIREMENTS

- 11.0.1 All personnel involved in the receipt, storage, testing, and release of primary packaging materials must be trained on this SOP.
- 11.0.2 Training must include a review of the SOP, the applicable regulatory requirements, and the company's quality standards.
- 11.0.3 Personnel must demonstrate competency in performing the tasks outlined in this SOP before being authorized to perform the tasks independently.
- 11.0.4 Training records must be maintained for all personnel.
- 11.0.5 Refresher training must be provided on a regular basis or when there are changes to the SOP or regulatory requirements.

12.0 REVIEW AND REVISION

- 12.0.1 This SOP will be reviewed at least annually or more frequently if there are changes to regulatory requirements, company policies, or the primary packaging material handling process.
- 12.0.2 The review will be conducted by the QA Manager.
- 12.0.3 Any revisions to the SOP must be approved by the Head of QA.
- 12.0.4 The revision history will be documented in the SOP.

13.0 APPROVALS

Prepared By: Packaging Engineer

Reviewed By: QA Manager

Approved By: Head of QA

Date: [Leave blank for manual completion]

Controlled Document Notice

This is a controlled document. Unauthorized reproduction, distribution, or alteration is prohibited. Ensure you are using the latest approved version.

Document Approval

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

Document Control Information

Document ID: SOP-PKG-001
Version: 2.0
Effective Date: 2025-01-01
Next Review Date: 2026-01-01
Generated by: NovaThera SOP Generator System