Document Type:	Standard Operating Procedure (SOP)	**SOP Code:**	SOP-WH-001
Title:	Receipt of Raw Materials and Packaging Components	**Version:**	2.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
Location:	Pune, India	**Review Date:**	2026-01-01

Receipt of Raw Materials and Packaging Components

Category: Materials Management

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Warehouse

Title: Receipt of Raw Materials and Packaging Components

SOP No.: SOP-WH-001

Version No.: 2.0

Effective Date: 2025-07-01

1.0 PURPOSE

This procedure outlines the standardized process for receiving raw materials and packaging components at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India, ensuring adherence to Current Good Manufacturing Practices (cGMP) and relevant regulatory guidelines (FDA, ICH Q7, Q9, Q10, WHO GMP). The procedure aims to ensure the identity, purity, safety, and efficacy of all raw materials and packaging components used in pharmaceutical manufacturing. This SOP establishes the quality controls required to prevent contamination, misidentification, and deterioration of materials, thereby safeguarding product quality and patient safety, and satisfying data integrity principles. The process includes visual inspection, verification of documentation, sampling, quarantine procedures, and appropriate storage conditions.

2.0 SCOPE

This SOP applies to all personnel involved in the receipt, inspection, sampling, and quarantine of raw materials and packaging components used in the manufacturing of all pharmaceutical products at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India. The scope includes but is not limited to active pharmaceutical ingredients (APIs), excipients, containers, closures, labels, and printed packaging materials. This SOP excludes the receipt of controlled substances, which are covered under

SOP-WH-002, and the receipt of equipment and machinery, which is covered under SOP-EN-001. This SOP ensures compliance with applicable regulatory requirements, including 21 CFR Parts 210 and 211, ICH Q7, Q9, Q10 guidelines, and WHO GMP guidelines. The process considers Quality by Design (QbD) principles and risk-based approaches to ensure consistent material quality and prevent potential deviations.

3.0 RESPONSIBILITY

QC Inspector: Responsible for performing visual inspection of received materials, verifying documentation (e.g., Certificate of Analysis, packing list), collecting samples according to the approved sampling plan (SOP-QC-003), and quarantining materials pending release. The QC Inspector must ensure all activities are documented accurately and completely in the receiving log and associated forms. The QC Inspector is responsible for maintaining a daily record of all inspections performed. The Inspector is accountable for alerting the QA Manager of any discrepancies or deviations detected during inspection. Quality metric: 100% of incoming raw materials and packaging components are inspected as per this SOP.

Production Supervisor: Responsible for overseeing the unloading of materials, ensuring materials are handled safely and correctly, coordinating with the Warehouse team for proper storage, and communicating with the QC Inspector to facilitate sampling. The Production Supervisor ensures that all personnel involved in the receiving process are trained and follow this SOP. The Supervisor has the authority to halt the receiving process if any critical deviations are observed (e.g., damaged containers, incorrect labeling).

QA Manager: Responsible for overseeing the implementation of this SOP, approving sampling plans, reviewing inspection reports and Certificate of Analysis (CoA), making release decisions for quarantined materials, investigating deviations, and ensuring appropriate corrective and preventative actions (CAPA) are implemented. The QA Manager ensures that this SOP is periodically reviewed and updated to reflect current regulatory requirements and best practices. The QA Manager also has the final authority for rejecting materials that do not meet specifications.

Head of QA: Responsible for providing strategic oversight of the quality system, ensuring compliance with all applicable regulations, acting as the primary liaison with regulatory agencies, approving major deviations and CAPAs, and ensuring that adequate resources are available to support the quality function. The Head of QA ensures that this SOP is aligned with the company's overall quality objectives and risk management strategy. The Head of QA ensures that all personnel involved in the receiving, inspection, and release of raw materials and packaging components are adequately trained and qualified.

4.0 MATERIALS & EQUIPMENT

PPE: Safety glasses (ANSI Z87.1 rated), safety shoes (steel-toed, EH rated), gloves (nitrile, powder-free, compliant with EN 374), lab coat (lint-free, compliant with ISO Class 8 cleanroom standards), and a dust mask (NIOSH approved N95 respirator) are required.

Equipment: Forklift (ELE-01, calibrated annually), pallet jack (PJ-01, inspected monthly), calibrated weighing scale (WSC-01, calibrated quarterly), calibrated temperature and humidity monitoring system (ENV-01, calibrated annually), sampling tools (stainless steel scoops,

spatulas, and containers, cleaned and sterilized before each use), calibrated thermometer (TMP-01, calibrated semi-annually), pH meter (PHM-01, calibrated daily prior to use), and a light box for visual inspection (LBX-01, inspected quarterly for correct illumination).

Documentation: Raw Material Receiving Log (Form WH-001-01, Version 2.0), Packaging Component Receiving Log (Form WH-001-02, Version 2.0), Material Inspection Checklist (Form QC-003-01, Version 2.0), Sampling Plan (SOP-QC-003), Certificate of Analysis (CoA) from the supplier, Purchase Order (PO), Material Safety Data Sheet (MSDS), Quarantine Release Form (Form QA-001-01, Version 2.0), Deviation Report (Form QA-002-01, Version 2.0), and Change Control Request Form (Form QA-003-01, Version 2.0). All forms and logs are electronic, stored in a validated system (LIMS-01) with audit trails and controlled access.

Reagents/Chemicals: Isopropyl alcohol (IPA, Pharma Grade, 70% v/v) for cleaning and sanitizing sampling tools and work surfaces. Distilled water (USP grade) for cleaning purposes.

5.0 PROCEDURE

5.1 Pre-Activity Preparation

5.1.1 Review the Purchase Order (PO) against the shipping manifest to verify the correct materials and quantities are expected.

5.1.2 Ensure the receiving area is clean, dry, and free from any potential contaminants. Clean and sanitize the area with 70% IPA and distilled water.

5.1.3 Verify that all required PPE is available and in good condition.

5.1.4 Ensure that all necessary equipment (forklift, pallet jack, weighing scale) is in good working order and within calibration. Calibration status to be verified against the calibration log and stickers present on the equipment.

5.1.5 Download and review the supplier's Certificate of Analysis (CoA) from the supplier portal. Verify the CoA meets NovaThera Pharmaceuticals' specifications.

5.1.6 Ensure the appropriate receiving logs and inspection checklists (electronic) are available in the LIMS system.

5.1.7 Check the environmental monitoring system (ENV-01) to ensure temperature and humidity are within acceptable limits (20-25°C and 40-60% RH). Record the temperature and humidity in the Receiving Log.

5.1.8 Inform the QC Inspector of the scheduled material arrival to allow for timely inspection and sampling.

5.2 Unloading and Initial Inspection

5.2.1 Upon arrival of the delivery vehicle, inspect the exterior of the vehicle for any signs of damage or contamination. Note any observations in the Receiving Log.

5.2.2 Carefully unload the materials using a forklift (ELE-01) or pallet jack (PJ-01), ensuring proper handling techniques to prevent damage.

5.2.3 Visually inspect each container for any signs of damage, tampering, or contamination (e.g., dents, tears, punctures, leaks). Record any discrepancies in the Receiving Log (Form WH-001-01 or WH-001-02).

5.2.4 Verify the material name, supplier, batch number, and quantity on each container label against the Purchase Order and shipping manifest.

5.2.5 Check the expiration date or retest date (if applicable) on the container labels. Ensure the material has sufficient remaining shelf life.

5.2.6 Segregate any damaged or suspect containers into a designated quarantine area.

5.2.7 Assign a unique Material Receipt Number (MRN) to each incoming shipment.

5.2.8 Record the MRN, material name, supplier, batch number, quantity, and date of receipt in the Receiving Log (Form WH-001-01 or WH-001-02). Enter this data directly into the electronic system (LIMS-01).

5.2.9 Affix a "Received" label with the MRN and date of receipt to each container.

5.2.10 Transfer the materials to the designated quarantine area.

5.3 Detailed Inspection and Sampling

5.3.1 The QC Inspector will perform a detailed inspection of the materials in the quarantine area.

5.3.2 Verify the integrity of the container seals and closures.

5.3.3 Verify the accuracy and legibility of the container labels.

5.3.4 Check the physical appearance of the material (e.g., color, odor, texture) against the material specification.

5.3.5 Verify the supplier's Certificate of Analysis (CoA) against the material specification. Check for completeness, accuracy, and compliance with regulatory requirements (e.g., test methods, acceptance criteria).

5.3.6 Take samples according to the approved sampling plan (SOP-QC-003). Use sterilized sampling tools (stainless steel scoops, spatulas) and containers.

5.3.7 Follow a statistically sound sampling plan based on the quantity of material received, complying with ANSI/ASQ Z1.4 standards.

5.3.8 Label each sample container with the MRN, material name, batch number, and date of sampling.

5.3.9 Record the sample details in the Sampling Log (Form QC-003-02).

5.3.10 Transport the samples to the QC laboratory for testing.

5.3.11 Update the status of the material in the LIMS system to "Awaiting QC Testing."

5.4 In-Process Controls

5.4.1 Temperature and Humidity Monitoring: Continuously monitor temperature and humidity in the receiving and quarantine areas using the calibrated monitoring system (ENV-01). Ensure temperature is maintained between 20-25°C and humidity between 40-60% RH. Record the readings every two hours.

5.4.2 Container Integrity Check: Verify the integrity of each container at every stage of the receiving process (unloading, inspection, sampling). Any damaged containers must be immediately segregated and documented.

5.4.3 Label Verification: Verify that all containers are correctly labeled with the correct material name, supplier, batch number, and quantity. Any discrepancies must be immediately reported and corrected.

5.4.4 Sampling Tool Sterilization: Ensure that all sampling tools are cleaned and sterilized before each use. Document the cleaning and sterilization process in the Equipment Log (Form EQ-001-01).

5.4.5 Documentation Review: Review all documentation (Purchase Order, shipping manifest, Certificate of Analysis) for completeness, accuracy, and compliance with regulatory requirements.

5.4.6 Acceptance Criteria: Materials must meet the following acceptance criteria to be released for use:

- All containers must be intact and undamaged.
- Labels must be accurate and legible.
- The supplier's CoA must meet NovaThera Pharmaceuticals' specifications.
- Sampling must be performed according to the approved sampling plan.
- Environmental conditions (temperature and humidity) must be within acceptable limits.

5.4.7 If any of the acceptance criteria are not met, a deviation must be initiated according to Section 10.0.

5.5 Quarantine and Release

5.5.1 The materials remain in quarantine until the QC laboratory completes all required testing and the QA Manager approves the release.

5.5.2 The QC laboratory will perform testing according to the material specification and approved test methods.

5.5.3 If the material meets all specifications, the QC laboratory will issue a Certificate of Analysis.

5.5.4 The QA Manager will review the QC laboratory's Certificate of Analysis, the Receiving Log, the Material Inspection Checklist, and the Sampling Log.

5.5.5 If all documentation is complete and the material meets all specifications, the QA Manager will approve the release of the material by completing the Quarantine Release Form (Form QA-001-01).

5.5.6 The Quarantine Release Form will be electronically signed and dated in the LIMS system.

5.5.7 Update the status of the material in the LIMS system to "Released."

5.5.8 Affix a "Released" label with the date of release to each container.

5.5.9 Transfer the released materials to the appropriate storage location in the warehouse, following FIFO (First In, First Out) principles.

5.5.10 Record the storage location in the LIMS system.

5.5.11 If the material does not meet specifications, a deviation will be initiated according to Section 10.0.

6.0 POST-ACTIVITY PROCEDURES

6.1 Review all documentation (Receiving Log, Material Inspection Checklist, Sampling Log, Quarantine Release Form) for completeness, accuracy, and compliance with data integrity principles (ALCOA+).

6.2 Ensure all data entries in the electronic system (LIMS-01) are accurate and complete.

6.3 Clean and sanitize all sampling tools and equipment with 70% IPA and distilled water.

6.4 Store the sampling tools and equipment in a clean and dry location.

6.5 Dispose of any waste materials (e.g., used gloves, wipes) according to the company's waste disposal procedures.

6.6 Update the material inventory records in the LIMS system.

6.7 File all documentation in the designated electronic folder on the shared drive. Maintain strict access control to ensure data security and integrity.

6.8 Perform a reconciliation of the received quantity against the Purchase Order and shipping manifest. Report any discrepancies to the Procurement department.

6.9 Review the temperature and humidity data recorded during the receiving process. Identify and address any excursions or trends that may indicate a potential problem.

6.10 Deactivate the Material Receipt Number (MRN) in the LIMS system after all activities are completed.

7.0 SAFETY PRECAUTIONS

7.1 Wear all required PPE (safety glasses, safety shoes, gloves, lab coat, dust mask) at all times during the receiving process.

7.2 Handle materials carefully to prevent damage or injury.

7.3 Use proper lifting techniques to avoid back injuries.

7.4 Be aware of potential hazards associated with the materials being handled (refer to the MSDS).

7.5 Follow all safety procedures for operating the forklift (ELE-01) or pallet jack (PJ-01).

7.6 In case of a spill or leak, contain the spill immediately and notify the Production Supervisor and QA Manager. Follow the company's spill control procedures.

7.7 In case of an injury, seek immediate medical attention and report the incident to the Safety Officer.

7.8 Ensure adequate ventilation in the receiving area to prevent the accumulation of hazardous fumes.

7.9 Use caution when handling containers with sharp edges or corners.

7.10 Store materials in a safe and secure manner to prevent accidents.

8.0 QUALITY CONTROL MEASURES

8.1 Sampling Plan: Follow the approved sampling plan (SOP-QC-003) for each material. The sampling plan should be based on a risk assessment and take into account the material's criticality, supplier history, and regulatory requirements.

8.2 Certificate of Analysis Review: Review the supplier's Certificate of Analysis (CoA) for completeness, accuracy, and compliance with NovaThera Pharmaceuticals' specifications. Verify that the test methods used are appropriate and validated.

8.3 Material Inspection: Perform a thorough visual inspection of each container and material. Check for any signs of damage, contamination, or tampering.

8.4 Testing: Perform all required testing on the samples in the QC laboratory according to the material specification and approved test methods.

8.5 Acceptance Criteria: Materials must meet all acceptance criteria specified in the material specification to be released for use.

8.6 Trend Analysis: Monitor the results of material testing over time to identify any trends or patterns that may indicate a potential problem.

8.7 Supplier Audits: Conduct periodic audits of suppliers to ensure they are following cGMP and meeting NovaThera Pharmaceuticals' quality requirements.

8.8 Environmental Monitoring: Regularly monitor the environmental conditions (temperature, humidity, particulate matter) in the receiving and quarantine areas.

8.9 Data Integrity: Ensure all data is recorded accurately, completely, and legibly. Follow ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, and Available).

8.10 Change Control: Any changes to the material specification, sampling plan, or test methods must be approved through the change control process (Form QA-003-01).

9.0 DOCUMENTATION AND RECORDS

9.1 Raw Material Receiving Log (Form WH-001-01, Version 2.0)

9.2 Packaging Component Receiving Log (Form WH-001-02, Version 2.0)

9.3 Material Inspection Checklist (Form QC-003-01, Version 2.0)

9.4 Sampling Plan (SOP-QC-003)

9.5 Sampling Log (Form QC-003-02)

9.6 Certificate of Analysis (CoA) from the supplier (electronic copy)

9.7 Purchase Order (PO) (electronic copy)

9.8 Material Safety Data Sheet (MSDS) (electronic copy)

9.9 Quarantine Release Form (Form QA-001-01, Version 2.0)

9.10 Deviation Report (Form QA-002-01, Version 2.0)

9.11 Change Control Request Form (Form QA-003-01, Version 2.0)

9.12 Equipment Calibration Logs (Form EQ-001-01)

9.13 Temperature and Humidity Monitoring Records (electronic)

9.14 All records must be maintained electronically in the LIMS system.

9.15 All records must be stored securely and protected from unauthorized access or alteration.

9.16 All records must be retained for a minimum of five years after the material is used or the product expires, whichever is longer, in accordance with regulatory requirements.

9.17 All records must be readily retrievable for review during audits and inspections.

9.18 Ensure all electronic records are compliant with 21 CFR Part 11 requirements, including audit trails, electronic signatures, and access controls.

10.0 DEVIATIONS AND CORRECTIVE ACTIONS

10.1 Any deviation from this SOP must be documented immediately on a Deviation Report (Form QA-002-01).

10.2 The Deviation Report must include a description of the deviation, the date and time of the deviation, the individuals involved, and the potential impact of the deviation.

10.3 The Production Supervisor and QA Manager must investigate the deviation to determine the root cause.

10.4 Appropriate corrective and preventative actions (CAPA) must be implemented to prevent recurrence of the deviation.

10.5 The CAPA must be documented on the Deviation Report and approved by the QA Manager and Head of QA.

10.6 The effectiveness of the CAPA must be monitored and documented.

10.7 All Deviation Reports must be reviewed and trended to identify potential systemic problems.

10.8 Deviation investigations must be initiated within 24 hours of the deviation being identified.

10.9 CAPA implementation must be completed within a timeframe appropriate to the severity of the deviation.

10.10 Deviation Reports must be closed out within 30 days of the deviation being identified.

11.0 TRAINING REQUIREMENTS

11.1 All personnel involved in the receipt, inspection, sampling, and quarantine of raw materials and packaging components must be trained on this SOP.

11.2 Training must be conducted by a qualified trainer and documented in the employee's training record.

11.3 Training must include both theoretical and practical components.

11.4 Training must be repeated annually or whenever the SOP is revised.

11.5 Specific training topics include:

- cGMP requirements
- This SOP (SOP-WH-001)
- Sampling Plan (SOP-QC-003)
- Material specifications
- Equipment operation and maintenance
- Safety procedures
- Data integrity
- Deviation reporting

11.6 Personnel must demonstrate competency in performing the tasks outlined in this SOP before being authorized to perform the tasks independently. Competency to be assessed through direct observation of the employee by the Production Supervisor or QA Manager.

12.0 REVIEW AND REVISION

12.1 This SOP must be reviewed at least annually by the QA Manager to ensure it remains current and compliant with regulatory requirements.

12.2 Revisions to this SOP must be approved by the QA Manager and Head of QA.

12.3 All revisions must be documented in the SOP revision history.

12.4 The current version of this SOP must be readily available to all personnel involved in the receipt, inspection, sampling, and quarantine of raw materials and packaging components via the company's document management system.

12.5 Change control procedures (Form QA-003-01) must be followed for all revisions to this SOP.

13.0 APPROVALS

Prepared By: QC Inspector

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-WH-001

Version: 2.0

Effective Date: 2025-01-01

Next Review Date: 2026-01-01

Generated by: NovaThera SOP Generator System