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Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
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Sampling of Raw Materials

Category: Quality Control Laboratory

Standard Operating Procedure (SOP)

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1.0 PURPOSE

This procedure defines the requirements for sampling raw materials at NovaThera Pharmaceuticals Pvt. Ltd. to ensure that representative samples are collected for quality control testing in accordance with Good Manufacturing Practices (GMP) for pharmaceutical manufacturing. This procedure aims to ensure the quality, safety, and efficacy of pharmaceutical products by verifying the identity, purity, and quality of raw materials used in production.

2.0 SCOPE

This SOP applies to all raw materials received at NovaThera Pharmaceuticals Pvt. Ltd. used in the manufacture of pharmaceutical products. It covers the procedures for sampling materials received in various types of containers, including but not limited to drums, bags, boxes, and containers. This procedure is applicable to all batches of raw materials irrespective of the vendor or product being manufactured. It does not cover the sampling of packaging materials or in-process materials, which are covered under separate SOPs.

3.0 RESPONSIBILITY

QC Inspector: Responsible for performing the sampling of raw materials according to this SOP, documenting the sampling process, and ensuring that samples are properly labeled and stored.

Production Supervisor: Responsible for coordinating with the QC Inspector to ensure timely access to raw materials for sampling and providing necessary support for the sampling process.

QA Manager: Responsible for reviewing and approving the sampling plan, ensuring that the SOP is followed, and investigating any deviations from the procedure.

Head of QA: Responsible for final approval of the SOP and any revisions, and for overseeing the overall quality control system.

4.0 MATERIALS & EQUIPMENT

PPE: Safety glasses, gloves (nitrile or appropriate material for the raw material being sampled), lab coats, dust mask or respirator (as required by the material's Safety Data Sheet (SDS)).

Equipment: Sampling thief (various sizes and materials e.g., stainless steel, plastic), sample containers (appropriate for the material being sampled, e.g., amber glass bottles, polyethylene bags), sterile spatulas, scoops, weighing balance (BAL-01), measuring cylinders, label printer, calibrated thermometer, calibrated hygrometer (HYG-01).

Documentation: Raw Material Sampling Form (NT-QC-F001), Raw Material Receiving Log (NT-WH-L001), Material Safety Data Sheets (MSDS), Cleaning Log (NT-QC-L002), Deviation Report Form (NT-QA-F001), Sample Submission Form (NT-QC-F002), Inventory Management System (IMS).

5.0 PROCEDURE

5.1 Preparation for Sampling

5.1.1 The Production Supervisor informs the QC Inspector of the raw materials arrival and availability for sampling, providing the necessary documentation, including the Certificate of Analysis (CoA) from the supplier and the Raw Material Receiving Log (NT-WH-L001).

5.1.2 The QC Inspector reviews the Raw Material Receiving Log (NT-WH-L001) and the supplier's CoA to verify the material's name, batch number, quantity, and storage conditions. Any discrepancies must be reported to the QA Manager immediately and resolved before proceeding with sampling.

5.1.3 The QC Inspector retrieves the Material Safety Data Sheet (MSDS) for the raw material to be sampled and reviews it for specific safety precautions and handling instructions.

5.1.4 The QC Inspector ensures that the sampling area is clean and free from any contaminants. The area must be cleaned according to the area's specific cleaning SOP and documented in the Cleaning Log (NT-QC-L002).

5.1.5 The QC Inspector verifies the calibration status of all equipment to be used, including the weighing balance (BAL-01), thermometer, and hygrometer (HYG-01), and records the calibration details on the Raw Material Sampling Form (NT-QC-F001).

5.1.6 The QC Inspector dons appropriate PPE, including safety glasses, gloves, lab coat, and dust mask or respirator (if required by the MSDS).

5.1.7 The QC Inspector prepares the necessary sample containers by labeling them with the following information:

- Material Name
- Batch Number
- Date of Sampling
- SOP Number (SOP-QC-001)
- Container Number (if applicable)
- Initials of the QC Inspector

5.2 Sampling from Drums or Large Containers

5.2.1 The QC Inspector selects the number of containers to be sampled based on the sampling plan outlined in NovaThera Pharmaceuticals' Raw Material Sampling Guidelines. The sampling plan considers factors such as batch size, material criticality, and supplier history. As a general guideline, use the formula: n = 1 + √N, where n is the number of containers to sample,

and N is the total number of containers.

5.2.2 For each container selected, the QC Inspector carefully opens the container using appropriate tools and techniques to avoid contamination.

5.2.3 Using a clean and sterile sampling thief of appropriate size, the QC Inspector inserts the thief into the material to obtain a representative sample from different locations within the container (e.g., top, middle, and bottom).

5.2.4 The QC Inspector dispenses the sample from the thief into the prepared sample container, ensuring that the container is not overfilled.

5.2.5 If the material is not homogeneous, the QC Inspector combines multiple samples from different locations within the container into a single composite sample.

5.2.6 The QC Inspector seals the sample container tightly and verifies that the label is securely attached and legible.

5.2.7 The QC Inspector closes the raw material container securely after sampling, ensuring that it is properly sealed to prevent contamination or degradation of the remaining material.

5.3 Sampling from Bags or Boxes

5.3.1 The QC Inspector selects the number of bags or boxes to be sampled based on the sampling plan outlined in NovaThera Pharmaceuticals' Raw Material Sampling Guidelines.

5.3.2 For each bag or box selected, the QC Inspector carefully opens the container using appropriate tools and techniques to avoid contamination.

5.3.3 Using a clean and sterile spatula or scoop, the QC Inspector takes a representative sample from different locations within the bag or box.

5.3.4 The QC Inspector transfers the sample into the prepared sample container, ensuring that the container is not overfilled.

5.3.5 If the material is not homogeneous, the QC Inspector combines multiple samples from different locations within the bag or box into a single composite sample.

5.3.6 The QC Inspector seals the sample container tightly and verifies that the label is securely attached and legible.

5.3.7 The QC Inspector closes the bag or box securely after sampling, ensuring that it is properly sealed to prevent contamination or degradation of the remaining material. If the original seal is broken during sampling, a new tamper-evident seal must be applied.

5.4 Documentation of Sampling

5.4.1 The QC Inspector records the following information on the Raw Material Sampling Form (NT-QC-F001):

- Material Name
- Batch Number
- Date of Sampling
- Time of Sampling
- Number of Containers Sampled
- Container Numbers (if applicable)
- Sampling Method Used
- Quantity of Sample Taken
- Ambient Temperature
- Ambient Humidity
- QC Inspector's Initials

• Any deviations from the SOP

5.4.2 The QC Inspector affixes a copy of the Raw Material Sampling Form (NT-QC-F001) to the sampled containers.

5.4.3 Any deviations from this SOP must be documented on a Deviation Report Form (NT-QA-F001) and submitted to the QA Manager for review and approval.

5.4.4 The QC Inspector updates the Inventory Management System (IMS) with the sampling information, including the date of sampling, the quantity of sample taken, and the status of the raw material (e.g., "sampled," "awaiting analysis").

5.5 Sample Submission and Storage

5.5.1 The QC Inspector submits the samples to the Quality Control Laboratory along with a completed Sample Submission Form (NT-QC-F002).

5.5.2 The Sample Submission Form (NT-QC-F002) includes the following information:

• Material Name
• Batch Number
• Date of Sampling
• SOP Number (SOP-QC-001)
• Analysis Required
• Storage Conditions
• QC Inspector's Initials

5.5.3 The QC Inspector ensures that the samples are stored under the appropriate conditions as specified in the raw material's storage requirements.

5.5.4 The QC Inspector maintains a record of all samples submitted to the laboratory, including the date of submission, the material name, the batch number, and the analysis required.

6.0 POST-SAMPLING ACTIVITIES

6.1 The QC Inspector returns all sampling equipment to its designated storage location.

6.2 The QC Inspector cleans all sampling equipment according to the equipment's cleaning SOP and documents the cleaning in the Cleaning Log (NT-QC-L002).

6.3 The QC Inspector removes and disposes of all used PPE according to the facility's waste disposal procedures.

6.4 The QC Inspector ensures that the sampling area is clean and free from any contaminants.

6.5 The Production Supervisor ensures that any partially used containers are properly resealed and labeled.

6.6 The QA Manager reviews the Raw Material Sampling Form (NT-QC-F001) and the Sample Submission Form (NT-QC-F002) to ensure that all information is complete and accurate.

6.7 The QA Manager files the completed Raw Material Sampling Form (NT-QC-F001) and Sample Submission Form (NT-QC-F002) in the appropriate records.

7.0 SAFETY PRECAUTIONS

7.1 Always review the Material Safety Data Sheet (MSDS) for the raw material before sampling.

7.2 Wear appropriate PPE, including safety glasses, gloves, lab coat, and dust mask or respirator (if required by the MSDS).

7.3 Avoid direct contact with the raw material.

7.4 Use caution when handling sampling tools to avoid injury.

7.5 Ensure that the sampling area is well-ventilated.

7.6 If any raw material spills, clean it up immediately according to the facility's spill control procedures.

7.7 Report any accidents or incidents to the Production Supervisor and the QA Manager immediately.

7.8 Be aware of potential fire hazards and ensure that flammable materials are handled in a designated flammable storage area.

7.9 Do not eat, drink, or smoke in the sampling area.

7.10 Dispose of used PPE and waste materials according to the facility's waste disposal procedures.

8.0 APPROVALS

Prepared By: QC Inspector

Reviewed By: QA Manager

Approved By: Head of QA

Date:

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