NovaThera Pharmaceuticals Pvt. Ltd.

Standard Operating Procedure (SOP)

Company:	NovaThera Pharmaceuticals Pvt. Ltd.
Department:	Quality Control Department
Title:	Sampling of Solid Raw Materials
SOP No.:	SOP-QC-SAM-001
Version No.:	1.0
Effective Date:	2025-03-01

1.0 PURPOSE

To lay down a unified and controlled procedure for the sampling of all solid raw materials. This SOP ensures the collection of a representative sample while preventing contamination of the sample and the bulk material, in full compliance with current Good Manufacturing Practices (cGMP).

2.0 SCOPE

This procedure is applicable to the sampling of all solid raw materials, including Active Pharmaceutical Ingredients (APIs) and Excipients (e.g., binders, fillers, lubricants, disintegrants), received in the designated Sampling Booths at NovaThera Pharmaceuticals Pvt. Ltd.

3.0 RESPONSIBILITY

QC Analyst / Authorized Personnel: To execute this SOP, perform the sampling activity, and complete all related logs (e.g., DVL-SB-01, SML-RM-01, CL-SB-01) contemporaneously.

QC Supervisor: To verify log entries, ensure personnel are adequately trained on this procedure, and manage scheduling (e.g., sampling campaigns).

QC Manager: To ensure overall compliance, resource availability, and training effectiveness.

Head of QA: To review and approve this SOP and perform periodic audits for compliance.

4.0 REGULATORY COMPLIANCE

US FDA - 21 CFR Part 211.84

EU GMP - Annex 1 & 8

ICH Q7, Section 7.3

5.0 MATERIALS & EQUIPMENT

PPE: Appropriate PPE as determined by the MSDS, including but not limited to: disposable lab coat, nitrile gloves, safety glasses/goggles, and a suitable respirator or dust mask.

Instruments: Calibrated Magnehelic Gauge, Calibrated Thermo-Hygrometer.

Sampling Tools: A set of sanitized stainless steel sampling tools (e.g., scoops, spatulas, slot samplers/triers), sterile sample bags/containers, security seals.

Cleaning Supplies: 70% Isopropyl Alcohol (IPA), lint-free wipes.

Documentation: Relevant logbooks "SAMPLED" labels, sample identification labels.

6.0 PROCEDURE

6.1 Pre-Sampling Checks

Prior to any sampling activity, the sampler shall:

- Review the Material Safety Data Sheet (MSDS) for the specific material to be sampled to understand all handling hazards and required PPE.
- Don the appropriate PPE as specified in the MSDS and Section 5.0.
- Verify the cleanliness of the Sampling Booth and equipment by checking the 'Area & Equipment Cleaning Log' (CL-SB-01).
- Switch on the Laminar Air Flow (LAF) of the booth and allow it to stabilize for at least 15 minutes.
- Verify and record the environmental conditions on the 'Daily Verification Log for Sampling Booth' (DVL-SB-01). The parameters must be within specifications:
  Differential Pressure: 10-15 Pascals
  Temperature: 20-25°C
  Relative Humidity: Not More Than 55% RH
- Do not proceed if any parameter is out of specification. Notify the QC Supervisor immediately.

6.2 Sampling Plan

- Review the Goods Receipt Note (GRN) to confirm the material identity, supplier, lot number, and the total number of containers received (n).
- Calculate the number of containers to be sampled using the sqrtn + 1 formula, rounding the result up to the next whole number. For single-container consignments, the container shall be sampled.
- Prepare the 'Raw Material Sampling Log' (SML-RM-01) with the required information.

6.3 Sampling Process

- Transfer only the containers selected for sampling into the Sampling Booth.
- Sanitize the outer surfaces of the containers and all sampling tools with 70% IPA.
- Working deliberately to minimize dust generation, carefully open the selected containers one by one.
- Using a sanitized sampling tool, withdraw the required quantity of material. For powders, samples should be taken from various locations (top, middle, bottom) to ensure representativeness.
- Transfer the collected material into a sterile sample bag or container. If a composite sample is required, combine portions from all sampled containers.
- Immediately and securely seal the sample container. Affix a completed identification label with all required details (Material Name, GRN No., Lot No., Sampled By, Date, etc.).
- Securely re-seal the bulk material containers. Affix a "SAMPLED" label to each container that was opened, noting the date and the sampler's initials.

6.4 Post-Sampling Activities

- Remove the sample and materials from the booth. Transfer the sample to the QC Laboratory with a completed sample submission form.
- Complete all entries in the 'Raw Material Sampling Log' (SML-RM-01) and ensure a unique Analytical Report (A.R.) Number is assigned.
- Thoroughly clean the sampling booth and all used equipment according to the relevant cleaning procedure. Pay special attention to removing residues from challenging materials (e.g., lubricants).
- Record the cleaning details in the 'Area & Equipment Cleaning Log' (CL-SB-01) and update the status of the booth to 'CLEANED'.

7.0 SAFETY PRECAUTIONS

- The Material Safety Data Sheet (MSDS) for each material MUST be consulted before handling. The MSDS is the primary source for specific hazard information and required safety controls.
- Always use the specified PPE to prevent inhalation, ingestion, or direct skin/eye contact.
- All sampling activities for open containers must be performed inside the energized sampling booth to ensure operator, environment, and material protection.

8.0 APPROVALS

Prepared By: Reviewed By: Approved By:

(Signature) (Signature) (Signature)

Name: Name: Name:

Title: QC Analyst Title: QC Manager Title: Head of QA

Date: Date: Date:

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