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# Sampling of In-Process Materials

**Category:** Quality Control Laboratory

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Quality Control Laboratory

**Title: Sampling of In-Process Materials**

SOP No.: SOP-QC-002

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## 1.0 PURPOSE

This procedure defines the standardized method for sampling in-process materials during pharmaceutical manufacturing at NovaThera Pharmaceuticals to ensure representative samples are collected for quality control testing, thereby maintaining product quality and adherence to GMP regulations.

## 2.0 SCOPE

This SOP applies to all in-process materials sampled during the manufacturing of pharmaceutical products at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India. This includes, but is not limited to, raw materials after dispensing, blended powders, granules, tablet cores, coated tablets, capsules, and liquid formulations at various stages of production, across all applicable batches and products manufactured. It excludes the sampling of finished products which is covered by a separate SOP.

## 3.0 RESPONSIBILITY

**QC Inspector:**

- Verifies the sampling request and ensures it aligns with the approved sampling plan.

- Collects in-process samples according to this SOP and the approved sampling plan.
- Documents all sampling activities accurately in the designated forms and registers.
- Ensures proper labeling and storage of collected samples.
- Reports any deviations or discrepancies observed during sampling to the Production Supervisor and QA Manager.
- Maintains cleanliness and functionality of sampling equipment.

**Production Supervisor:**

- Initiates sampling requests as per the manufacturing schedule and approved sampling plan.
- Notifies the QC Inspector of the need for sampling.
- Ensures the in-process materials are readily accessible for sampling.
- Investigates any deviations reported by the QC Inspector related to the in-process materials or sampling process.

**QA Manager:**

- Reviews and approves the sampling plan for each product.
- Oversees the implementation of this SOP and ensures compliance with GMP regulations.
- Investigates deviations related to sampling and approves corrective and preventive actions (CAPA).
- Provides training on this SOP to relevant personnel.
- Periodically reviews this SOP to ensure its effectiveness and relevance.

**Head of QA:**

- Provides final approval for this SOP and any revisions.
- Ensures that adequate resources are available for the implementation of this SOP.
- Oversees the overall quality system and ensures compliance with regulatory requirements.

## 4.0 MATERIALS & EQUIPMENT

**PPE:**

- Disposable gloves (nitrile or latex, as appropriate for the material being sampled)
- Safety glasses or goggles
- Dust mask or respirator (as required based on the material's Material Safety Data Sheet (MSDS))
- Lab coat or gown
- Shoe covers

**Equipment:**

- Stainless steel sampling scoops (various sizes)
- Stainless steel sampling spoons

- Sampling thief (for powders and granules)
- Sterile sample containers (e.g., wide-mouth bottles, bags)
- Labels (pre-printed with product name, batch number, sample ID, date, time, and sampler's initials)
- Permanent marker
- Isopropyl alcohol (IPA) (70% v/v) for cleaning
- Lint-free wipes
- Calibrated weighing balance (if required for quantitative sampling)
- Portable Laminar Air Flow (LAF) unit (if required based on risk assessment)
- Thermometer (calibrated) for temperature monitoring (if required)

**Documentation:**

- Sampling Request Form (NT-QF-001)
- In-Process Material Sampling Logbook (NT-LR-002)
- Material Safety Data Sheets (MSDS) for all materials being sampled
- Approved Sampling Plan for the specific product
- Equipment Cleaning Log (NT-LR-003)
- Deviation Report Form (NT-QF-002)

## 5.0 PROCEDURE

### 5.1 Preparation for Sampling

#### 5.1.1 The Production Supervisor initiates a Sampling Request Form (NT-QF-001) as per the approved manufacturing schedule and sampling plan.

#### 5.1.2 The Production Supervisor ensures that the in-process material is readily accessible for sampling and notifies the QC Inspector.

#### 5.1.3 The QC Inspector reviews the Sampling Request Form (NT-QF-001) and verifies that it aligns with the approved sampling plan.

#### 5.1.4 The QC Inspector obtains the necessary PPE and ensures it is in good condition.

**5.1.5 The QC Inspector gathers the required sampling equipment, including scoops, spoons, sampling thief, sterile sample containers, labels, permanent marker, IPA, and lint-free wipes.**

**5.1.6 The QC Inspector verifies the cleanliness of the sampling equipment. If necessary, clean the equipment with IPA and lint-free wipes and allow it to air dry completely before use. Record the cleaning in the Equipment Cleaning Log (NT-LR-003).**

**5.1.7 If sampling requires a Portable LAF unit, the QC Inspector ensures it is operational and certified.**

**5.1.8 The QC Inspector reviews the Material Safety Data Sheet (MSDS) for the material to be sampled to understand any specific safety precautions.**

**5.2 Sampling of Blended Powders (BLN-04)**

**5.2.1 The QC Inspector dons the appropriate PPE, including gloves, safety glasses, dust mask (if required), lab coat, and shoe covers.**

**5.2.2 Ensure the blender (BLN-04) is stopped and locked out/tagged out according to safety procedures.**

**5.2.3 Using a clean sampling thief, insert the thief into the powder bed at multiple locations (top, middle, and bottom) to obtain a representative sample. The sampling plan will dictate the number and location of sampling points.**

**5.2.4 Carefully withdraw the sampling thief and dispense the powder into a pre-labeled sterile sample container.**

**5.2.5 Ensure the sample container is properly sealed.**

**5.2.6 Visually inspect the sample for any abnormalities (e.g., foreign matter, agglomerates). Record any observations in the In-Process Material Sampling Logbook (NT-LR-002).**

**5.2.7 Label the sample container with the product name, batch number, sample ID, date, time, and sampler's initials using a permanent marker.**

**5.2.8 Record the sampling details in the In-Process Material Sampling Logbook (NT-LR-002), including the location of sampling points, the quantity of sample taken, and any observations.**

**5.3 Sampling of Granules**

**5.3.1 The QC Inspector dons the appropriate PPE, including gloves, safety glasses, dust mask (if required), lab coat, and shoe covers.**

**5.3.2 Using a clean stainless steel scoop, collect granules from multiple locations within the granulator or container. The sampling plan will dictate the number and location of sampling points.**

**5.3.3 Dispense the granules into a pre-labeled sterile sample container.**

**5.3.4 Ensure the sample container is properly sealed.**

**5.3.5 Visually inspect the sample for any abnormalities (e.g., foreign matter, oversized granules, fines). Record any observations in the In-Process Material Sampling Logbook (NT-LR-002).**

**5.3.6 Label the sample container with the product name, batch number, sample ID, date, time, and sampler's initials using a permanent marker.**

**5.3.7 Record the sampling details in the In-Process Material Sampling Logbook (NT-LR-002), including the location of sampling points, the quantity of sample taken, and any observations.**

**5.4 Sampling of Tablet Cores (TCP-01)**

**5.4.1 The QC Inspector dons the appropriate PPE, including gloves, safety glasses, lab coat, and shoe covers.**

**5.4.2 Collect tablet cores randomly from the tablet press discharge chute (TCP-01) or collection container at predetermined intervals as specified in the sampling plan.**

**5.4.3 Collect the required number of tablet cores as specified in the sampling plan.**

**5.4.4 Place the tablet cores into a pre-labeled sterile sample container.**

**5.4.5 Ensure the sample container is properly sealed.**

**5.4.6 Visually inspect the tablet cores for any defects (e.g., capping, lamination, chipping). Record any observations in the In-Process Material Sampling Logbook (NT-LR-002).**

**5.4.7 Label the sample container with the product name, batch number, sample ID, date, time, and sampler's initials using a permanent marker.**

**5.4.8 Record the sampling details in the In-Process Material Sampling Logbook (NT-LR-002), including the time of sampling, the number of tablets collected, and any observations.**

**5.5 Sampling of Coated Tablets**

**5.5.1 The QC Inspector dons the appropriate PPE, including gloves, safety glasses, lab coat, and shoe covers.**

**5.5.2 Collect coated tablets randomly from the coating pan discharge or collection container at predetermined intervals as specified in the sampling plan.**

**5.5.3 Collect the required number of coated tablets as specified in the sampling plan.**

**5.5.4 Place the coated tablets into a pre-labeled sterile sample container.**

**5.5.5 Ensure the sample container is properly sealed.**

**5.5.6 Visually inspect the coated tablets for any defects (e.g., uneven coating, cracking, color variation). Record any observations in the In-Process Material Sampling Logbook (NT-LR-002).**

**5.5.7 Label the sample container with the product name, batch number, sample ID, date, time, and sampler's initials using a permanent marker.**

**5.5.8 Record the sampling details in the In-Process Material Sampling Logbook (NT-LR-002), including the time of sampling, the number of tablets collected, and any observations.**

**5.6 Sampling of Capsules**

**5.6.1 The QC Inspector dons the appropriate PPE, including gloves, safety glasses, lab coat, and shoe covers.**

**5.6.2 Collect capsules randomly from the capsule filling machine discharge or collection container at predetermined intervals as specified in the**

**sampling plan.**

**5.6.3 Collect the required number of capsules as specified in the sampling plan.**

**5.6.4 Place the capsules into a pre-labeled sterile sample container.**

**5.6.5 Ensure the sample container is properly sealed.**

**5.6.6 Visually inspect the capsules for any defects (e.g., dents, cracks, incomplete filling). Record any observations in the In-Process Material Sampling Logbook (NT-LR-002).**

**5.6.7 Label the sample container with the product name, batch number, sample ID, date, time, and sampler's initials using a permanent marker.**

**5.6.8 Record the sampling details in the In-Process Material Sampling Logbook (NT-LR-002), including the time of sampling, the number of capsules collected, and any observations.**

**5.7 Sampling of Liquid Formulations**

**5.7.1 The QC Inspector dons the appropriate PPE, including gloves, safety glasses, lab coat, and shoe covers.**

**5.7.2 Ensure the liquid formulation is adequately mixed before sampling.**

**5.7.3 Using a sterile syringe or a clean stainless steel sampling tube, collect the liquid formulation from multiple locations within the mixing vessel or container. The sampling plan will dictate the number and location of sampling points.**

**5.7.4 Dispense the liquid formulation into a pre-labeled sterile sample container.**

**5.7.5 Ensure the sample container is properly sealed.**

**5.7.6 Visually inspect the sample for any abnormalities (e.g., particulates, phase separation). Record any observations in the In-Process Material Sampling Logbook (NT-LR-002).**

**5.7.7 If required, measure the temperature of the liquid formulation using a calibrated thermometer and record the temperature in the In-Process Material Sampling Logbook (NT-LR-002).**

**5.7.8 Label the sample container with the product name, batch number, sample ID, date, time, and sampler's initials using a permanent marker.**

**5.7.9 Record the sampling details in the In-Process Material Sampling Logbook (NT-LR-002), including the location of sampling points, the quantity of sample taken, temperature (if measured), and any observations.**

## 6.0 POST-SAMPLING ACTIVITIES

6.1 The QC Inspector delivers the collected samples to the Quality Control Laboratory for testing.

6.2 The QC Inspector records the date and time of sample delivery in the In-Process Material Sampling Logbook (NT-LR-002).

6.3 The QC Inspector cleans the sampling equipment with IPA and lint-free wipes and stores it in a designated area. Record the cleaning in the Equipment Cleaning Log (NT-LR-003).

6.4 The QC Inspector removes and disposes of used PPE according to established waste disposal procedures.

6.5 The Production Supervisor verifies that the sampling process was completed according to the approved sampling plan and this SOP.

6.6 If any deviations occurred during the sampling process, the QC Inspector and Production Supervisor initiate a Deviation Report Form (NT-QF-002) and forward it to the QA Manager for investigation and corrective action.

## 7.0 SAFETY PRECAUTIONS

7.1 Always wear appropriate PPE when sampling in-process materials.

7.2 Refer to the Material Safety Data Sheet (MSDS) for each material to understand the specific hazards and safety precautions.

7.3 Use caution when handling sharp objects, such as sampling thieves and syringes.

7.4 Ensure adequate ventilation when sampling powders or materials that may generate dust.

7.5 Avoid contact with hazardous materials. If contact occurs, wash the affected area immediately with soap and water and seek medical attention if necessary.

7.6 Dispose of used PPE and waste materials according to established waste disposal procedures.

7.7 Immediately report any spills or accidents to the Production Supervisor and QA Manager.

7.8 Lock out/Tag out procedures must be followed before sampling from any energized equipment, like blenders or tablet presses.

## 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 |
|---|---|---|---|
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| Reviewed by (QA): | _____ | _____ | _____ |
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