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Title:	Sampling of Finished Products	**Version:**	1.0
Company:	NovaThera Pharmaceuticals Pvt. Ltd.	**Effective Date:**	2025-01-01
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Sampling of Finished Products

Category: Quality Control Laboratory

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Quality Control Laboratory

Title: Sampling of Finished Products

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1.0 PURPOSE

This procedure defines the standardized method for the representative sampling of finished pharmaceutical products at NovaThera Pharmaceuticals, ensuring compliance with Good Manufacturing Practices (GMP) and adherence to regulatory guidelines for accurate quality control testing and product release in pharmaceutical manufacturing.

2.0 SCOPE

This Standard Operating Procedure (SOP) applies to all finished pharmaceutical products manufactured and packaged at NovaThera Pharmaceuticals Pvt. Ltd., Pune, India, including tablets, capsules, liquids, creams, and ointments. This SOP covers the procedures for obtaining representative samples from finished product batches prior to release for distribution, regardless of batch size or product type. This SOP excludes sampling of raw materials, in-process materials, and packaging components, which are covered by separate SOPs.

3.0 RESPONSIBILITY

QC Inspector:

- Collects samples of finished products according to this SOP.
- Ensures the cleanliness and suitability of sampling tools and equipment.
- Documents the sampling process accurately and completely in the appropriate forms and registers.
- Labels all collected samples clearly and accurately.
- Stores samples appropriately to maintain their integrity.
- Reports any deviations from this SOP to the QA Manager.
- Ensures appropriate area cleaning after sampling.

Production Supervisor:

- Provides access to the finished product batches for sampling.
- Notifies the QC Inspector when finished product batches are ready for sampling.
- Ensures the finished product batches are stored in the designated quarantine area prior to sampling.
- Reviews sampling documentation for completeness and accuracy.
- Assists in the investigation of any sampling discrepancies.

QA Manager:

- Reviews and approves this SOP and any revisions.
- Oversees the implementation of this SOP and ensures compliance with GMP regulations.
- Investigates and resolves any deviations from this SOP.
- Ensures that QC Inspectors are adequately trained on this SOP.
- Periodically audits the sampling process to ensure adherence to this SOP.

Head of QA:

- Provides final approval for this SOP.
- Oversees the quality assurance functions related to sampling of finished products.
- Ensures that adequate resources are available for the implementation of this SOP.
- Makes final decisions regarding deviations or investigations related to this SOP.

4.0 MATERIALS & EQUIPMENT

PPE:

- Cleanroom gown
- Hairnet
- Face mask
- Safety glasses or goggles
- Powder-free nitrile gloves

Equipment:

- Sampling scoops (various sizes, stainless steel, autoclavable)
- Sampling spatulas (stainless steel, autoclavable)
- Sample containers (amber glass or HDPE bottles, sterile, with tamper-evident closures)
- Sterile bags (various sizes, autoclavable)
- Label printer
- Balance (ACC-01, calibrated)
- Cleaning solutions (e.g., 70% Isopropyl Alcohol)
- Portable sampling booth (if required for potent compounds)
- Vacuum cleaner with HEPA filter
- Stainless steel trolley

Documentation:

- Finished Product Sampling Form (F-QC-003-01)
- Sample Register (R-QC-001)
- Equipment Cleaning Log (L-QC-002)
- Batch Manufacturing Record (BMR)
- Product Specification Sheet
- Deviation Report Form (F-QA-001)

5.0 PROCEDURE

5.1 Preparation for Sampling

5.1.1 The Production Supervisor shall notify the QC Inspector that a batch of finished product is ready for sampling and available in the designated quarantine area.

5.1.2 The QC Inspector shall review the Batch Manufacturing Record (BMR) and the Product Specification Sheet for the product to be sampled.

5.1.3 The QC Inspector shall verify the batch number, product name, manufacturing date, and expiry date against the BMR.

5.1.4 The QC Inspector shall ensure that all sampling equipment is clean, dry, and in good working order. Refer to Equipment Cleaning Log (L-QC-002) for cleaning records.

5.1.5 The QC Inspector shall gather all necessary materials and equipment, including PPE, sampling tools, sample containers, labels, and the Finished Product Sampling Form (F-QC-003-01).

5.1.6 The QC Inspector shall don the appropriate PPE, including a cleanroom gown, hairnet, face mask, safety glasses or goggles, and powder-free nitrile gloves.

5.1.7 The QC Inspector shall clean the external surfaces of the containers of the finished product to be sampled with 70% Isopropyl Alcohol and allow to air dry.

5.1.8 If sampling potent compounds, the QC Inspector shall set up a portable sampling booth in a designated area.

5.2 Sampling of Tablets and Capsules

5.2.1 Determine the number of containers to be sampled based on a statistically valid sampling plan. A minimum of square root of ‘n+1’ where ‘n’ is the number of containers should be taken, however a risk based approach may be taken for determining the number of containers to be sampled and should be documented.

5.2.2 For tablets/capsules in bottles, select the required number of bottles randomly from the batch.

5.2.3 For tablets/capsules in blister packs, select the required number of blister packs randomly from different cartons and cases.

5.2.4 Open each selected container carefully to avoid contamination.

5.2.5 Using a clean sampling scoop or spatula, withdraw a representative sample from each selected container. The sample should be taken from different locations within the container (top, middle, and bottom).

5.2.6 The total quantity of tablets/capsules to be taken as a sample should be as per the product specification and testing requirements.

5.2.7 Place the collected sample into a pre-labeled sample container. The label should include the following information:

- Product Name
- Batch Number
- Date of Sampling
- Time of Sampling
- Sampling Location
- Sampler's Signature
- SOP Number

5.2.8 Close the sample container tightly and ensure that it is properly sealed.

5.2.9 Record the details of the sampling process on the Finished Product Sampling Form (F-QC-003-01), including the container numbers sampled, the quantity of sample taken from each container, and any observations made during the sampling process.

5.3 Sampling of Liquids, Creams, and Ointments

5.3.1 Determine the number of containers to be sampled based on a statistically valid sampling plan. A minimum of square root of ‘n+1’ where ‘n’ is the number of containers should be taken, however a risk based approach may be taken for determining the number of containers to be sampled and should be documented.

5.3.2 For liquids, creams and ointments in bottles, jars, or tubes, select the required number of containers randomly from the batch.

5.3.3 Ensure that the product is homogeneous before sampling. If necessary, gently mix the product using a sterile spatula or mixer (BLN-04), avoiding the introduction of air bubbles.

5.3.4 Open each selected container carefully to avoid contamination.

5.3.5 Using a clean sampling scoop or spatula, withdraw a representative sample from each selected container. The sample should be taken from different locations within the container (top, middle, and bottom).

5.3.6 The total quantity of liquid, cream, or ointment to be taken as a sample should be as per the product specification and testing requirements.

5.3.7 Place the collected sample into a pre-labeled sample container. The label should include the following information:

- Product Name
- Batch Number
- Date of Sampling
- Time of Sampling
- Sampling Location
- Sampler's Signature
- SOP Number

5.3.8 Close the sample container tightly and ensure that it is properly sealed.

5.3.9 Record the details of the sampling process on the Finished Product Sampling Form (F-QC-003-01), including the container numbers sampled, the quantity of sample taken from each container, and any observations made during the sampling process.

5.4 Sample Handling and Storage

5.4.1 After sampling, the QC Inspector shall immediately transport the samples to the Quality Control Laboratory.

5.4.2 The QC Inspector shall record the sample details in the Sample Register (R-QC-001), including the date and time of receipt, the product name, the batch number, and the tests to be performed.

5.4.3 The QC Inspector shall store the samples under the appropriate storage conditions as specified in the Product Specification Sheet (e.g., room temperature, refrigerated).

5.4.4 The QC Inspector shall ensure that the samples are protected from light, moisture, and other environmental factors that could affect their integrity.

5.4.5 If samples need to be shipped to an external testing laboratory, the QC Inspector shall follow the procedures outlined in SOP-QC-005 (Shipping of Samples).

6.0 POST-SAMPLING ACTIVITIES

6.1 The QC Inspector shall ensure that all sampling tools and equipment are cleaned and sanitized according to SOP-QC-004 (Cleaning and Sanitization of Laboratory Equipment).

6.2 The QC Inspector shall dispose of any used PPE in the designated waste containers.

6.3 The QC Inspector shall clean the sampling area with appropriate cleaning solutions and allow to air dry.

6.4 The Production Supervisor shall return the sampled finished product batch to the designated quarantine area.

6.5 The QC Inspector shall submit the Finished Product Sampling Form (F-QC-003-01) and the Sample Register (R-QC-001) to the QA Manager for review.

6.6 The QA Manager shall review the sampling documentation for completeness and accuracy.

6.7 The QA Manager shall notify the laboratory personnel to begin testing the samples according to the approved testing procedures.

6.8 All deviations identified during the sampling process shall be documented in a Deviation Report Form (F-QA-001) and investigated by the QA Manager.

7.0 SAFETY PRECAUTIONS

7.1 Wear appropriate PPE at all times during the sampling process.

7.2 Handle all pharmaceutical products with care to avoid contamination.

7.3 Avoid direct contact with the product. Use sampling tools to withdraw samples.

7.4 Be aware of the potential hazards associated with the product being sampled (e.g., irritants, sensitizers, potent compounds). Refer to the Material Safety Data Sheet (MSDS) for specific safety information.

7.5 If sampling potent compounds, use a portable sampling booth and follow all safety procedures outlined in SOP-EH-001 (Handling of Potent Compounds).

7.6 Dispose of waste materials properly in designated containers.

7.7 Clean up any spills immediately using appropriate cleaning solutions.

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

7.9 Ensure proper ventilation in the sampling area.

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

7.11 Wash hands thoroughly with soap and water after sampling.

7.12 If working with products manufactured using the TCP-01 or SFT-02, inspect for any metal shavings or abnormalities prior to beginning the procedure.

8.0 APPROVALS

Prepared By: QC Inspector

Reviewed By: QA Manager

Approved By: Head of QA

Date:

Document Approval

Role	Name	Signature	Date
Prepared by:	_____	_____	_____
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