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Sampling of Primary and Secondary Packaging Materials

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Quality Control Department

Title: Sampling of Primary and Secondary Packaging Materials

SOP No.: SOP-QC-SAM-002

Version No.: 1.0

Effective Date: 2025-01-01

1.0 PURPOSE

To lay down a unified and controlled procedure for the sampling of all primary and secondary packaging materials. This SOP ensures the collection of a representative sample for quality control testing while preventing contamination or damage to the bulk material, in full compliance with cGMP.

2.0 SCOPE

This procedure is applicable to the sampling of all received primary packaging materials (e.g., PVC/PVDC Film, Aluminium Lidding Foil) and secondary packaging materials (e.g., Printed Cartons, Patient Information Leaflets) in the designated warehouse quarantine and inspection areas at NovaThera Pharmaceuticals Pvt. Ltd.

3.0 RESPONSIBILITY

- QC Inspector / Authorized Personnel:** To execute this SOP, perform the sampling activity, and complete all related logs contemporaneously.
- QC Supervisor:** To verify log entries, ensure personnel are trained, and manage the sampling schedule.
- QC Manager:** To ensure overall compliance and resource availability.
- Head of QA:** To review and approve this SOP.

4.0 REGULATORY COMPLIANCE

- US FDA - 21 CFR Part 211.84
- ISO 2859-1: Sampling procedures for inspection by attributes.

5.0 MATERIALS & EQUIPMENT

- PPE:** Disposable lab coat, nitrile gloves, safety glasses.
- Inspection Area:** A dedicated, clean, well-lit inspection table in the quarantine warehouse.
- Sampling Tools:** Calibrated ruler/tape measure, Pantone color guide, barcode scanner, sharp safety knife/blade, sample bags, security seals.
- Documentation:** Relevant GRNs, QC Register, "SAMPLED" labels, sample identification labels.

6.0 PROCEDURE

6.1 Pre-Sampling Checks

Prior to any sampling activity, the QC Inspector shall:

- Review the Goods Receipt Note (GRN) and the supplier's Certificate of Analysis (COA/CoC) for the material to be sampled.
- Don the appropriate PPE as specified in Section 5.0.
- Ensure the inspection table is clean, clear of other materials, and suitable for use.

6.2 Sampling Plan

1. Review the GRN to confirm the material identity, supplier, lot number, and the total number of containers/bundles received (n).
2. Calculate the number of containers/bundles to be sampled using the $\sqrt{n} + 1$ formula, rounding up. For single-container consignments, that container shall be sampled.
3. Determine the number of individual units to sample from each selected container as per the material-specific plan below.

6.3 Sampling Process - By Material Type

A) For Rolled Goods (PVC/PVDC Film, Aluminium Foil):

1. Transfer the selected roll to a clean, secure unwinding station.
2. Carefully remove the outer protective wrapping.
3. Discard the first 3-5 layers of the roll as is standard practice to avoid sampling surface contamination.
4. Using a sharp safety knife and a ruler, carefully cut a **1-meter long strip** across the full width of the roll.
5. Place the sample strip into a clean, labeled sample bag.
6. Securely re-wrap and seal the bulk material roll. Affix a "SAMPLED" label to the roll, noting the date and sampler's initials.

B) For Printed Components (Printed Cartons, PILs):

1. Select the required number of bundles as calculated in 6.2.
2. From each selected bundle, randomly select **10 individual units** (cartons or leaflets).
3. Visually inspect each unit for obvious defects (e.g., damage, misprints).
4. Place the collected sample units into a clean, labeled sample bag.
5. Securely re-seal the original bundles. Affix a "SAMPLED" label to each bundle that was opened.

6.4 Post-Sampling Activities

1. Transfer the collected samples to the QC Laboratory with a completed sample submission form.
2. Update the **QC Register** with the sampling details (date, quantity, sampler).
3. Ensure the bulk material is returned to its designated quarantine location.

7.0 SAFETY PRECAUTIONS

- Use caution when handling large, heavy rolls of foil and film.
- Use a sharp safety knife with care when cutting samples to avoid personal injury.
- Always wear gloves to prevent contamination of the packaging materials.

8.0 APPROVALS

	≡ Prepared By:	≡ Reviewed By:	≡ Approved By:
1	Name: Priya Soni	Name: Anjali Mehta	Name: Rohan Desai
2	Title: QC Analyst	Title: QC Manager	Title: Head of QA
3	Date:	Date:	Date:

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