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Sampling of Rolled Packaging Materials

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Quality Control Department

Title: Sampling of Rolled Packaging Materials

SOP No.: SOP-QC-SAM-003

Version No.: 1.0

Effective Date: 2025-01-01

1.0 PURPOSE

To lay down a controlled and repeatable procedure for the sampling of rolled primary packaging materials, such as Aluminium Foil and PVC/PVDC Film. This SOP ensures the collection of a representative sample for quality control testing while maintaining the integrity and cleanliness of the bulk roll.

2.0 SCOPE

This procedure is applicable to all rolled packaging materials received in the warehouse quarantine area at NovaThera Pharmaceuticals Pvt. Ltd.

3.0 RESPONSIBILITY

- **QC Inspector:** To execute this SOP, perform the sampling, and complete all related documentation.
- **Warehouse Operator:** To assist the QC Inspector with the safe movement and handling of the heavy rolls.
- **QC Supervisor:** To ensure compliance and training.

4.0 MATERIALS & EQUIPMENT

- **PPE:** Safety shoes, safety glasses, cut-resistant gloves.
- **Inspection Area:** A dedicated, clean, well-lit roll inspection station with an unwinding jig.
- **Sampling Tools:** Calibrated measuring tape, sharp safety knife/blade with a fresh blade, lint-free wipes, 70% IPA, sample bags, security seals.
- **Documentation:** Relevant GRN, QC Register, "SAMPLED" labels, sample identification labels.

5.0 PROCEDURE

5.1 Pre-Sampling Checks

1. The QC Inspector shall review the GRN and the supplier's COA for the roll to be sampled.
2. The QC Inspector and Warehouse Operator shall don the appropriate PPE.
3. Verify that the roll inspection station is clean and free from other materials.

5.2 Sampling Process

1. With assistance from the Warehouse Operator, safely transport the selected roll (e.g., GRN-PM-25-001 for PVC Film) to the inspection station and securely mount it on the unwinding jig.
2. Carefully cut and remove the outer protective wrapping (e.g., shrink wrap, paper).
3. **Discard Initial Layers:** Unwind and discard the first **five full rotations** of the material from the roll. This is a critical step to eliminate any surface material that may have been exposed to the environment or handling.
4. **Measure and Cut Sample:** Using a calibrated measuring tape, measure a **1.5-meter length** of the film/foil.
5. Using the safety knife, make a clean, straight cut across the full width of the web to obtain the sample.
6. **Sample Handling:** Immediately place the 1.5-meter sample strip into a large, clean, labeled sample bag. The label must include: Material Name, Lot No., GRN No., Sampled By, and Date.

- 7. **Secure the Bulk Roll:** Carefully re-wrap the bulk roll with its protective wrapping. If the original wrapping is unusable, use new, approved protective wrapping. Securely tape the end of the roll to prevent it from unwinding.
- 8. **Labeling:** Affix a "SAMPLED" label to the outer wrapping of the bulk roll. The label must include the date and the sampler's initials.
- 9. With assistance from the Warehouse Operator, safely return the bulk roll to its designated quarantine location.

6.0 Post-Sampling Activities

- 1. Transfer the collected sample to the QC Laboratory.
- 2. Update the QC Register with the sampling details.
- 3. Clean the inspection station and any tools used.

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

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