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Sampling of Corrugated Shipper Cases

SOP for Sampling of Shipper Cases

Standard Operating Procedure (SOP)

Company: NovaThera Pharmaceuticals Pvt. Ltd.

Department: Quality Control Department

Title: Sampling of Corrugated Shipper Cases

SOP No.: SOP-QC-SAM-004

Version No.: 1.0

Effective Date: 2025-01-01

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1.0 PURPOSE

To define the procedure for sampling corrugated shipper cases to verify their quality, dimensions, and print accuracy against established specifications.

2.0 SCOPE

This procedure is applicable to all lots of corrugated shipper cases received in the warehouse quarantine area.

3.0 RESPONSIBILITY

- QC Inspector: To execute this SOP.

4.0 MATERIALS & EQUIPMENT

- PPE: Safety glasses, gloves.
- Inspection Area: A clean, flat, well-lit inspection table.
- Sampling Tools: Calibrated measuring tape, safety knife.
- Documentation: Relevant GRN, QC Register, "SAMPLED" labels.

5.0 PROCEDURE

5.1 Sampling Plan

- Review the GRN to confirm the total number of bundles received (n).
- Calculate the number of bundles to sample using the $\sqrt{n} + 1$ formula, rounding up. (e.g., For 4 bundles received, sample $\sqrt{4} + 1 = 3$ bundles).
- From each selected bundle, take two shipper cases from different positions (e.g., one from the top, one from the middle).

5.2 Sampling Process

1. Transport the selected bundles to the inspection area.
2. Carefully cut the straps on the selected bundles.
3. Withdraw the required number of flat shipper cases (e.g., 3 bundles * 2 cases/bundle = 6 cases total).
4. **Perform Initial Inspection:** Visually inspect each sampled case for obvious defects like moisture damage, tears, or improper gluing.
5. **Assemble One Case:** Take one of the sampled cases and erect it into its final box shape to check for proper scoring and fit.
6. **Sample Handling:** Place the remaining flat cases and the one erected case together as the official sample. Affix a sample identification label to the top case.
7. **Secure the Bulk Material:** Re-strap the opened bundles securely.
8. **Labeling:** Affix a "SAMPLED" label to each of the opened bundles.
9. Return all bundles to their designated quarantine location.

6.0 Post-Sampling Activities

1. Transfer the collected sample cases to the QC Laboratory for full dimensional and print verification.
2. Update the QC Register with the sampling details.

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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