

Standard Operating Procedure

Secondary Packaging Operations

1. Purpose

This Standard Operating Procedure (SOP) describes the steps and guidelines for conducting secondary packaging operations in order to ensure product integrity, compliance with regulatory requirements, and consistent quality.

2. Scope

This SOP applies to all personnel involved in secondary packaging activities for finished pharmaceutical products in the packaging department.

3. Responsibilities

- **Packaging Operators:** Perform secondary packaging as per SOP and batch record.
- **Line Supervisors:** Ensure compliance, monitor staff, and complete relevant documentation.
- **Quality Assurance:** Review operations and records, and authorize batch release.

4. Definitions

- **Secondary Packaging:** Packaging of the already packed products into cartons, boxes, or overwraps for final presentation and shipping.

5. Materials & Equipment

1. Product units in primary packaging
2. Cartons, boxes, leaflets, and labeling materials
3. Taping machine, carton sealer, and labeling device
4. Personal protective equipment (PPE)
5. Documentation (batch packing records)

6. Procedure

1. Verify the availability of all required packaging materials as per batch record.
2. Ensure packaging line clearance and cleanliness before starting operations.
3. Wear the required PPE before entering the packaging area.
4. Inspect packaging materials for damage or contamination.
5. Arrange packaging materials and products as per layout plan.
6. Begin secondary packaging by placing primary units into cartons as per specifications.
7. Add inserts or leaflets where required.
8. Seal cartons using approved methods (taping, gluing).
9. Label secondary packages with required batch information.

10. Inspect packed cartons for completeness and integrity.
11. Record observations and quantities in batch record.
12. Transfer completed packages to the next stage or storage as directed.
13. Clean the packaging area at the completion of operations.

7. Documentation

- Batch Packaging Record
- Packaging Material Issue/Return Record
- Line Clearance Checklists

8. Safety & Precautions

- Always use PPE during operations.
- Report any deviation or non-compliance to the supervisor immediately.
- Keep the workplace clean to avoid mix-ups and contamination.

9. Attachments/Forms

Refer to current versions of the necessary records and checklists.

10. Revision History

| Version | Date | Description | Approved By |
|---------|------------|---------------------|-------------|
| 1.0 | 2024-06-05 | Initial SOP Release | QA Manager |