

Standard Operating Procedure (SOP)

Primary Packaging

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1. Purpose

To define the procedure for conducting primary packaging of finished goods to ensure product safety, quality, and integrity.

2. Scope

This SOP applies to all personnel involved in the primary packaging process within the packaging department.

3. Responsibilities

- **Packaging Operator:** To perform packaging as per this SOP and report any anomalies.
- **Quality Assurance:** To verify compliance with specifications and production records.
- **Supervisor:** To ensure process adherence and provide necessary resources.

4. Definitions

- **Primary Packaging:** The first layer of packaging in immediate contact with the product (e.g., bottle, blister, sachet).

5. Procedure

1. Verify the cleanliness of the packaging area and equipment before use.
2. Confirm the availability and quality of primary packaging materials as per the batch record.
3. Wear appropriate personal protective equipment (PPE) before entering the packaging zone.
4. Set up the packaging line as per instructions and check for correct labels, leaflets, and materials.
5. Start the packaging process following the approved work instructions.
6. Conduct in-process checks:
 - Visual inspection of product and packaging materials.
 - Verification of label information and batch details.
 - Periodic count and reconciliation of packaging units.
7. Segregate any rejected materials and record non-conformities as per quality procedures.
8. Upon completion, clean equipment and the area, and document the operation in relevant records.

6. Documentation

- Batch Packaging Record
- Cleaning Checklist
- Label Reconciliation Form

7. Safety & Precautions

- Always use prescribed PPE.
- Handle materials gently to avoid damage.
- Report any deviation or incident immediately.

8. References

- GMP Guidelines
- Company Quality Manual

9. Revision History

Version	Date	Change Description
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