

# Standard Operating Procedure (SOP)

## Primary Packaging

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<b>Revision No.</b>	00	<b>Page No.</b>	1 of 1

### 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

- Verify the cleanliness of the packaging area and equipment before use.
- Confirm the availability and quality of primary packaging materials as per the batch record.
- Wear appropriate personal protective equipment (PPE) before entering the packaging zone.
- Set up the packaging line as per instructions and check for correct labels, leaflets, and materials.
- Start the packaging process following the approved work instructions.
- 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.
- Segregate any rejected materials and record non-conformities as per quality procedures.
- 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
00	YYYY-MM-DD	Original Issue

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Approved by