

Standard Operating Procedure (SOP)

Label Generation, Verification, and Issuance Controls

This SOP details **label generation, verification, and issuance controls** to ensure accurate and consistent labeling of products. It covers the procedures for generating labels, verifying label content for correctness and compliance with regulatory standards, and controlling the issuance of labels to avoid errors or mislabeling. The goal is to maintain product traceability, uphold quality standards, and prevent labeling discrepancies throughout the production and distribution process.

1. Purpose

To ensure all product labels are generated, verified, and issued in accordance with internal procedures and regulatory requirements, maintaining product identity, traceability, and quality.

2. Scope

This SOP applies to all personnel involved in label creation, review, approval, and issuance for products manufactured and distributed by [Company Name].

3. Responsibilities

Role	Responsibility
Label Coordinator	Generate and maintain accurate label templates per approved masters.
Quality Assurance (QA)	Verify label content, approve labels, and oversee issuance controls.
Production Staff	Request, receive, and apply issued labels as per work orders.
Regulatory Affairs	Ensure label compliance with applicable regulatory standards.

4. Definitions

- Label:** Any printed or electronic document affixed to product packaging, containing required product information.
- Master Label:** The approved version of a label used as a reference for all production labels.
- Issuance:** The process of releasing approved labels for production use.

5. Procedure

5.1 Label Generation

- Obtain label content from product specifications, regulatory requirements, and approved artwork.
- Design the label using standardized templates and approved design software.
- Submit draft labels to Regulatory Affairs for initial regulatory review.
- Save all label drafts and versions in the designated document control system.

5.2 Label Verification

- Quality Assurance reviews label content for accuracy (product name, batch/lot number, expiry date, etc.), legibility, and overall compliance.
- Verify the content matches product specifications, master documentation, and regulatory requirements.
- Document verification using an approved checklist. Address any discrepancies prior to approval.
- Regulatory Affairs reviews and confirms compliance as needed.

5.3 Label Approval & Issuance Controls

- Obtain final QA and Regulatory Affairs approval; archive approved labels with signatures/dates.
- Label Coordinator prepares and numbers labels according to production batch/work order.
- Issue labels only to authorized production staff. Record quantities and recipient details in the label log.
- Unused labels must be returned to the Label Coordinator for reconciliation and destruction or re-use according to company policy.
- Perform periodic audits of label issuance records and unused label inventory.

6. Documentation & Records

- Label generation and approval records
- Label verification checklists
- Label issuance logs
- Label reconciliation records

7. References

- Applicable local and international regulatory labeling guidelines (e.g., FDA, EMA, etc.)
- [Company Name] Document Control Procedure

8. Revision History

Version	Date	Description	Approved By
1.0	[Insert Date]	Initial release	[Name/Title]