		Pure Nutra Labs 65 Crest Ridge Drive, Suwanee, GA, 30024	
Title: Product Identification, Traceability & Mock Recall		Approved By: Quality Director	
Policy #: SOP-0024	Issue Date: 09/06/2025	Revision: 2	Page 1 of 5

Purpose:

The product identification system shall be implemented to ensure raw materials, packaging, work in progress (WIP) and finished product are clearly identified during all stages of receipt, production, storage and dispatch, and that finished product is labeled to the customer specification and regulatory requirements. This will ensure that finished products are accounted for and easily identified in the event there are customer or regulatory concerns.

Scope:

All products including raw materials, WIP, and finished products during all stages of production and storage.

Definition:

M#: Unique, sequential identifying code that is assigned to raw materials at receipt.


Responsibility:

Quality Management - Responsible for implementing the program and ensuring annual compliance.

Production Employees & QC – responsible for recording lot numbers for materials used in the relevant worksheets

Procedures:

- I. All related documents and records will be kept for 4 years for traceability and review.

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II. Incoming Raw Materials

- A. Incoming product is assigned an M# if it is an ingredient.
- B. The internal M#, which is assigned to the materials, is specified in the sequence of receipt. The M# is used to identify the vendor, the external lot#, etc.
- C. The date of receipt of raw materials will be recorded by QC and the CoA will be scanned and filed in the QC folder.

III. Packaging materials (food contact packaging and materials) will be received by production managers and the related documents will be kept in the production managers' office.


- A. Bottles - The manufacturer's lot number of the bottles and other packaging products will be recorded and traced back to the external lot# as the bottles are labeled and coded.
- B. Cotton, lid, droppers, and silica - The manufacturer's lot number and lot# of the packaging material will be traced back to the PO# as they are being bottled.

IV. Finished Products

- A. Each finished product has its unique lot#, which is assigned to the product in the sequence of production. The lot # will have the initial letter to abbreviate the product name and the number will represent the order it is done.
- B. The finished product lot number consists of two random letters and the PO number.

V. Compounding

- A. A 4x4 white sticker is used to identify the product with Product Name, PO#, Batch Number and Color. The compounding room number will be recorded.

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VI. Mixing


- A. A 4x4 white sticker is used to identify the product with Product Name, PO#, Batch Number and Color. In mixing, the capsule type and color is added.

VII. Encapsulating/Pressing

- A. A 4x4 white sticker is used to identify the product with Product Name, PO#, Batch Number, WIP Number, and Color. In mixing, the capsule type and color is added. The polisher and room number will be recorded on the batch sheet for traceability and review.

VIII. Packaging

- A. The lot number is legibly written onto the finished packaging with an inkjet.
- B. The packaging line number will be recorded for traceability and review.
- C. The product identification records (PO details) will be maintained for 4 years.
- D. Finished products may have an expiration date printed next to the lot code.
- E. Inspection of finished product and packaging will be documented.
- F. Box labels contain customer driven data, which may include the company name, customer name and address, and production date.
- G. Labeled retains are held from segments throughout the run, labeled with the box number they represent, and are kept for a year in the event post manufacturing sampling is required.
- H. In the end, all stages of production are documented or are traceable using the batching and MMR sheets.

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I. Sanitation records are kept on file in the Sanitation Manager’s office.

IX. Shipping

- A. The shipping documents will be kept for 4 years for traceability and review.
- B. The plant documents the lot numbers and amount of product shipped on the BOLs. Distribution records will be kept in the production managers’ office.
- C. In the appropriate data sheet, the amount, type and lot numbers are documented.

X. Rework

- A. When the product is reworked, the lot# / PO# will be used to trace back to M# and the external lot#.

XI. Bulk

- A. When used, bulk products are identified using the same system of traceability, except that a sticker is used as the final lot code and description of the product which includes the PO# / M# for traceability and review.

XII. Traceability Exercise (Mock Recall)

- A. Finished product trace exercises shall encompass finished product lot trace-back to the first level of distribution and a trace of raw ingredients through production (one up and one down). These exercises will be done at least annually.
- B. Raw material, including food contact packaging, trace exercises shall encompass raw material trace-forward to all finished products in which it was used and stored.
- C. Finished product traceability exercises will be traced to the first level of distribution (e.g. warehouse).



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- D. All traceability exercises will demonstrate a 99.5% to 101.5% recovery, taking into account normal loss, waste or shrinkage. When outside of these specifications, actions will be included to perform root cause analysis and subsequent corrections of any issues identified.
- E. Traceability exercises are not to exceed four (4) hours.
- F. Records of the trace activity with supporting data will be maintained.
- G. A mock scenario shall be conducted with a traceability exercise once per year. The mock scenario should involve the recall team and simulate the steps taken in a real recall.

Document History

Revision #	Review Date	Description of Change	Reviewer Name
1	03/05/2025	New procedure.	Chad Hinson, Quality Director
2	09/06/2025	Updated company name.	Chad Hinson, Quality Director

Approvals:

Chad Hinson

Chad Hinson (Sep 7, 2025 17:20:34 EDT)

Title: CTO

Sam Holguin

Sam Holguin (Sep 7, 2025 12:48:41 EDT)

Title: CEO

Jh

Jh Blankenship (Sep 7, 2025 20:06:16 EDT)

Title: COO










SOP-0024r2 Product Identification and Traceability


Final Audit Report

2025-09-08

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