		Norax Supplements 655 10th St. Cedartown, GA 30125	
Title: Product Identification and Traceability		Approved By: Plant Manager	
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1.0 Purpose

1.1 The product identification system shall be implemented to ensure raw materials, packaging, work in progress 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. Each unique lot of raw materials and finished products are accounted for. This will ensure that finished products are accounted for and easily identified in the event there are customer or regulatory concerns.

2.0 Scope

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

3.0 Definition


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

4.0 Responsibility


4.1 QA Director- Responsible for implementing the program and ensuring annual compliance.
4.2 Production Employees & QC – responsible for recording lot numbers for materials used in the relevant worksheets

5.0 Procedures

5.1 All related documents & records will be kept for 4 years for traceability and review.
5.2 Incoming raw materials
5.2.1 Incoming product is assigned an M# if it is an ingredient.
5.2.2 The internal m# which is assigned to the materials is specified in a sequence of receipt. The M# is used to identify the vendor, the external lot#, etc.
5.2.3 A sticker will be applied with R#, M#, Date Received, Expiration Date, Allergen Status, Organic Status.
5.2.4 The date of receipt of raw materials will be recorded by QC and the CoA will be scanned and filed in the Hold & Release Incoming Raw Material Smartsheet.
5.3 Packaging materials (the food contact packaging and materials will be received and inspected by the Purchasing Department and the related documents will be kept in the)

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- 5.3.1 Bottles- The manufacturer’s lot number of the bottles and other packaging products will be recorded in DataCor and are used in a lot specific manner that allows for full trace back.
- 5.3.2 Cotton, lid, droppers, and silica- The manufacturer’s lot number of the packaging and excipient materials will be documented as they are being bottled.
- 5.4 Compounding
 - 5.4.1 A 4X4 white sticker is used to identify the product with Product Name, PO#, Batch Number and Color. Compounding room number will be recorded.
 - 5.4.2 There is a sticker that is applied to say ready for Mixing after QC tests are passed.
- 5.5 Mixing
 - 5.5.1 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.
 - 5.5.2 There is a sticker that is applied to say ready for Compounding after QC tests are passed.
- 5.6 Encapsulating/Pressing
 - 5.6.1 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 & room number will be recorded on the batch sheet for traceability and review
- 5.7 Packaging Finished Product
 - 5.7.1 The lot number is legibly written onto the finished packaging with an inkjet printer and verified by QC.
 - 5.7.2 Each product will have a unique lot code composed of one or two letter abbreviation of the product name, the last four digits of the purchase order number, the Julian date, and the line number which the product was produced. The basic sequence should be XX#### - ### - #
 - 5.7.3 The expiration date will be printed in a MM/DD/YYYY format. The expiration date will be one month prior from the manufacturing date, the 28th of the month, and the number of years subsequent from the date of manufacturing (~3 years) For example, a product manufactured on 12/15/2021 will have an expiration date of 11/28/2024.
 - 5.7.4 The product identification records (PO details) will be maintained for 4 years.
 - 5.7.5 Inspection of finished product and packaging will be documented.

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- 5.7.6 Box Labels contain customer driven data which will include our name; customer name and address; and production date.
- 5.7.7 Labeled retains are held from segments throughout the run; these are labeled with the box number they represent and are kept for a year in the event post manufacturing sampling is required.
- 5.7.8 In the end, all stages of production are documented or are traceable using the batch record.

5.8 Shipping

- 5.8.1 The shipping documents will be kept for 4 years for traceability and review.
- 5.8.2 The plant documents the lot numbers & amount of product shipped on the BOLs. Distribution records will be kept in the production managers' office.

5.9 Rework


- 5.9.1 When the product is reworked, the lot#/po# will be used to trace back to m# and the external lot#.

5.10 Bulk

- 5.10.1 When used, bulk product is 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.

5.11 Traceability Exercise

- 5.11.1 Finished product trace exercises shall encompass finished product lot trace-back to the first level of distribution. These exercises will be done at least twice annually.
- 5.11.2 Raw material, including food contact packaging, trace exercise shall encompass raw material trace-forward to all finished product in which it was used and stored.
- 5.11.3 Finished product traceability exercises will be traced to the first level of distribution (IE warehouse)
- 5.11.4 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 will include actions to perform root cause analysis and subsequent corrections of any issues identified
- 5.11.5 Traceability exercises are not exceed for (4) hours
- 5.11.6 Records of the trace activity with supporting data will be maintained.

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6.0 Document History

Revision #	Review Date	Description of Change	Reviewer Name
1	11/11/2019	New	Aaron Choi, Quality Control Director
2	11/14/2020	Reviewed	Aaron Choi, Quality Control Director
3	5/20/2022	Added new Finished Product labeling requirements and raw material stickering.	Steven Ray, QC Director.
4	3/24/2023	Clarified Lot Coding Procedures	Kayla Faust, Compliance Specialist