



1343 N. Colorado Street, Suite  
111 Gilbert, AZ 85233

## Packaging & Labeling Operations

Effective Date: January 20, 2021  
Created Date: August 28, 2019  
Date Revised: December 29, 2020  
Version Number: 02

QSOP-025

Page 1 of 5

<https://prenexushealth.sharepoint.com/sites/QA/Shared Documents/Certification docs/Halal/Halal World Watch/2022/Document Submission/Traceability Docs/QSOP-025 PACKAGING AND LABELING OPERATIONS.doc>

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### TABLE OF CONTENTS

<u>SECTION</u>	<u>PAGE</u>
1. Purpose .....	2
2. Scope.....	2
3. Responsibilities.....	2
4. Procedure .....	2
4.1. Packaging and Label Requirements .....	2
4.2. Filling, Assembling, Packaging, Labeling, and Operations .....	3
4.3. Documented Net Weight and/or Count Compliance .....	3
4.4. Manufacturing Codes on Individual and Cased Product .....	4
4.5. Package Integrity and Function .....	4
4.6. Tamper-Evident Packaging.....	4
4.7. Repackaging and Relabeling .....	4
4.8. Rejected Packaged and Labeled Dietary Supplements .....	5
5. History of Changes .....	5

### 1. PURPOSE

To describe the requirements and guidelines for filling, assembling, packaging and labeling of dietary supplement products in order to ensure integrity of products, use of correct packaging and labels, accurate product weights and count compliance.

### 2. SCOPE

The requirements detailed in this SOP for packaging and labeling operations apply to all dietary supplement products packaged at main production facilities, as well as at all satellite facilities.

### 3. RESPONSIBILITIES

Production Management, Quality Assurance and Quality Control are responsibilities for enforcing the requirements of this procedure in the filling, assembling, packaging and labeling of dietary supplement products.

### 4. PROCEDURE

#### 4.1. Packaging and Labeling Requirements

- 4.1.1. Issuance of packaging and labeling components that meet specifications must be done in a manner that ensures reconciliation.
- 4.1.2. Prior to use, packaging components and labels must be examined to determine if they conform to product specifications.
- 4.1.3. The Packaging Line Operator must verify use of the correct labels at pre-established intervals.
- 4.1.4. Documented Quality Assurance checks must also be conducted at regularly scheduled intervals to verify use of the correct labels.

#### 4.2. Filling, Assembling, Packaging, Labeling Operations

- 4.2.1. Packaging and labeling operations must be segregated from other operations to prevent cross-contamination. Packaging and labeling operations must also be segregated from raw materials, in process materials, finished products and non-food items to minimize risk of contamination.
- 4.2.2. Filling and packaging equipment must be cleaned per established cleaning procedures prior to start of packaging operations.
- 4.2.3. Documented inspections of packaging lines must be performed by Production and verified by Quality Assurance to ensure that:

- 4.2.3.1. Packaging equipment has been cleaned.
- 4.2.3.2. Packaging equipment has been inspected and properly assembled.
- 4.2.3.3. Surrounding areas have been thoroughly cleaned and are free of debris.
- 4.2.3.4. All labels from the previous run have been removed.
- 4.2.4. A representative sample of each batch of packaged and labeled dietary supplements must be examined to determine whether the dietary supplement meets specifications.
- 4.3. Documented Net Weight
  - 4.3.1. Compliance with label claim for net weights, count or volume for packaged finished products must be established by any one of the following methods:
    - 4.3.1.1. Each container of a product sold by weight must meet the weight specified on the label. To ensure that each container meets label claim, all containers must be weighed using calibrated scales that are verified daily.
- 4.4. Manufacturing Codes on Individual and Cased Product
  - 4.4.1. Individual sell units of dietary supplements, as well as product cases must be labeled with unique lot numbers for proper management and traceability of production lots. The individual package codes and product case codes must be the same.
  - 4.4.2. All product coding and expiration dates must be of such size, color and contrast to afford easy legibility at a reasonable distance.
  - 4.4.3. Lot number sequencing must be consistent and well documented.
  - 4.4.4. Packaged dietary supplement containers that are set aside and held in unlabeled condition for future label operations must be identifying by an effective means to prevent mix-ups.
- 4.5. Package Integrity and Function
  - 4.5.1. Individual sell unit packaging and shipping cases must be properly sized, designed and assembled to be suitable for their application and provide the necessary protection for the product from environmental and shipping conditions.



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Page 4 of 5

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4.5.2. Production line operators must check the integrity of at least one shipping case of product, as well as the integrity of the individual containers in the case at regularly scheduled intervals. Checks should ensure that containers are properly closed and sealed without evidence of leaks.

4.5.3. Documentation must be available describing the test methods, specifications, and results of all container integrity testing.

4.5.4. Product cases stored in warehouses should show no evidence of leaking or staining, and they should not bulge or crease due to stacking.

### 4.6. Tamper-Evident Packaging

4.6.1. Tamper evident packaging requirements (e.g. inner cap seals, heat-shrinkable neck bands, sealed bags, and security seals for bulk containers) must be included in the product specifications; and specific item codes for each tamper evident component must appear on the packaging batch sheet.

4.6.2. To ensure their effectiveness, tamper evident features should be checked as part of the regularly scheduled quality checks performed by packaging line operators, and by Quality Assurance. All checks of tamper evident features must be clearly documented on the batch record.

### 4.7. Repackaging and Relabeling

4.7.1. Dietary supplements may be repackaged or re-labeled only with Quality Assurance approval.

4.7.2. A representative sample of each batch of repackaged or relabeled dietary supplements must be examined to determine compliance with established specifications established.

4.7.3. Quality Control must approve or reject each batch of repackaged or relabeled dietary supplement prior to its release for distribution.

### 4.8. Rejected Packaged and Labeled Dietary Supplements

Any packaged and labeled dietary supplement that is rejected for distribution must be clearly identified, held and control under quarantine for appropriate disposition.

## 5. HISTORY OF CHANGES

Date of Change	Change Description	Justification	Supersedes Version No.	New Version No.	Approval Initials



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Page 5 of 5

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