1.0 Purpose

This procedure defines the process for receiving raw materials (including bulk finished product received for packaging only), packaging and printed packaging into the warehouse and assignment of unique identifying numbers to each receipt.

2.0 Scope

This procedure applies to raw materials (including bulk finished product received for packaging only) and packaging components received for manufacture and packaging of dietary supplements, pet products, drugs, and cosmetics. This procedure does not apply to equipment, laboratory chemicals, or ordinary business orders.

3.0 Responsibility

3.1 It is the responsibility of Warehouse personnel to follow this procedure.

3.2 It is the responsibility of Quality to make final the determination of the suitability of all materials.

3.3 It is the responsibility of the QC Laboratory to ensure that data logger information is recorded upon receipt of raw material, if applicable.

4.0 Definitions

4.1 **PO** – Purchase Order

4.2 **R#** – Receiving Number; a unique identifying number assigned to raw materials and packaging components upon receipt

4.3 **RM** – Raw Material

4.4 **COA** – Certificate of Analysis

4.5 **COC** – Certificate of Compliance

4.6 **DC** – Document Control

4.7 **BOL** – Bill of Lading

5.0 References

5.1 E-801, SOP, Return of Materials and Destruction of Non-Hazardous Waste Materials

5.2 E-901, SOP, Shipping and Receiving Transport Inspection

5.3 E-901-F1, Form, Trailer Inspection Log

5.4 21 CFR Part 111, 211

6.0 Procedure

6.1 Purchasing will make available in Batchmaster approved POs to warehouse personnel.

Note: If allergens are ordered, the item master will be set up with detailed information.

6.1.1 Purchasing will request appropriate component technical drawings and specifications from the supplier and forward them to Production for approval and retention.

6.2 The warehouse associate will compare incoming materials to the packing list and Batchmaster item description. The warehouse will place into QC Hold any material that does not match for quality, grade, material description, or manufacturer/distributor name. Purchasing/Quality will be notified of the discrepancy and will determine the suitability of the material.

6.2.1 Partial orders may be accepted. However, unique R#s must be assigned to materials delivered on different days, even if they are the same manufacturer's lot #.

6.2.2 Visually inspect the received items(s) for damage and/or broken seals. Verify the count and weight received against the PO, to confirm ordered quantity. If any discrepancy is noted, notify Purchasing Department and Quality immediately.

6.2.3 If damage is observed and the identity, composition, or purity is in question, the material(s) will be placed into QC Hold. Note any damages on the BOL and attach photographs to the email notification.

6.2.4 Damages must be noted on the BOL for all freight inbound orders. Photographs of the damage must be taken as soon as it is seen. The warehouse should obtain a claim number from the freight carrier if available. Notify Shipping and Purchasing of any damages. The damaged material(s) are to be placed into QC Hold. Follow SOP E-801 Return of Materials and Destruction of Non-Hazardous Waste Materials or for disposition of the damaged materials.

6.3 If a COA or COC is received with the order, it is to be given to Quality for inclusion with the test record. Quality will contact Purchasing to acquire certifications on materials that were not initially delivered.

6.4 All incoming raw materials (including bulk finished product received for packaging only) and packaging (including printed packaging) will be entered into the electronic inventory system and assigned a sequential auto-generated number in the format of R#####. The electronic inventory system contains the following information:

6.4.1 R#

6.4.2 Date/Time Received

6.4.3 Material Name

6.4.4 Allergen (if applicable)

6.4.5 Non GMO Project Verified (if applicable)

6.4.6 Certified Organic (if applicable)

6.4.7 Kosher (if applicable)

6.4.8 Halal (if applicable)

6.4.9 Gluten (if applicable)

6.4.10 Quantity

6.4.11 Manufacturer/Vendor

6.4.12 Manufacturer/Vendor's Lot #

6.4.13 PO #

6.4.14 Goods Receipt Document Number

6.4.15 Received By

6.5 The warehouse creates barcoded labels for the raw material and packaging component containers indicating the material ID#, material name matching the PO, R#, Vendor name, and Vendor Lot#. A label is then placed onto each container of the material.

6.6 The warehouse records the R# and a goods receipt document number on the packing list and electronically scans them to the following folder location: F:\RECEIVING PAPERWORK.

Note: Materials that contain allergens are stored in a separate area, away from non-allergens in the warehouse and/or according to manufacturer's specific requirements. Materials that are used for Non-GMO Project Verified, Certified Organic, Kosher or Halal products will be stored separately. Materials that are

Gluten or may contain gluten will be stored separately.

6.7 Should raw material or packaging components be received in an environmentally controlled transport truck, and a data logger is provided, the data logger will be delivered immediately to the QC lab. The data will be promptly download and placed in the raw material release packet. In the event a data logger is not provided the temperature will be checked by the designated warehouse associate with a calibrated thermometer and the temperature will be recorded onto Form E-901-F1 Trailer Inspection Log. Refer to SOP E-901 Shipping and Receiving Transport Inspection.

6.8 Storage Conditions must be as reflected in the CofA. Product received with no temperature referenced on CoA will not require special storage conditions. Should an excursion occur, it is at the discretion of the customer and QC Laboratory to decide if the material is to be received and used.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	04/13/11	New	-	-
1	04/04/13	Changed the SOP format and number. Updated SOP format.	-	-
2	08/01/13	Added form E-204-F2. Added in section 5.12 "Expiration Date".	-	-
3	12/13/13	Added sections 5.2.2 and 5.2.3. Added purchasing to section 5.2. Added ID# to section 5.11.1 and Form E-204-F1	13-1168	M. Wienke
4	04/16/14	Added section for allergen materials. Updated SOP format.	14-0332	M. Wienke
5	09/10/14	Added step for the request of technical drawings and specifications.	14-0729	S. Millar
6	09/08/16	Biennial review: Reworded for clarity.	16-0791	W. Asbell
7	11/29/16	Added reference to nonprescription drugs and cosmetics	16-1091	E. Hasanbasic
8	01/09/19	Remove R-card requirements. Updated to reflect Batchmaster processes.	19-0032	J. Murphy
9	10/01/20	Procedure Rewrite to include label control receiving process. Removed incoming log.	CC-20-0699	J. Murphy
10	04/29/21	Added Non GMO Project Verified comments to section 6.1, 6.4 and 6.6. Added temperature information in section 6.7	CC-21-0169	C. Mitchell
11	08/10/21	Added CFR reference. Added comments in reference to bulk finished product received for packaging.	CC-21-0320	C. Mitchell
12	11/02/21	Added references to Certified Organic, Kosher and Halal in sections 6.4 and 6.6	CC-21-0424	C. Mitchell
13	11/30/22	Added packaging components to scope of procedure. Changed SOP title. Clarified procedure throughout.	CC-22-0456	J. Murphy
14	08/15/23	Added materials that are Gluten or may contain gluten to be store separately to Section 6.6 notes.	CC-23-0415	C. Horelle