1.0 Purpose

The purpose of this procedure is to define the process for the allocation, storage, and annual inventory of all received raw materials, packaging components, and printed packaging.

2.0 Scope

This procedure applies to all raw materials, packaging components and printed packaging stored at Ion Labs, Inc.

3.0 Responsibility

3.1 Purchasing, Warehouse and Inventory Control personnel are responsible for the overall inventory management and compliance with this procedure.

3.2 It is the responsibility of Warehouse management or designee to request raw materials, packaging components, and printed packaging for batches.

3.3 It is the responsibility of Warehouse personnel to pull and restock inventory.

3.4 It is the responsibility of Warehouse management to implement this procedure and to ensure that the procedure is being followed.

4.0 Definitions

4.1 **Allocation** – The process of identifying materials in inventory and selectively placing them for use in a batch

4.2 **Packaging Components and Printed Packaging** – Any component intended for

packaging related activity in the manufacture of dietary supplements

4.3 **RMID** – Raw Material Identification Number; a unique identifier used to tack inventory within a business

4.4 **R# -** Receiving Number; A unique identifying number assigned to each lot of material upon receipt

4.5 **DC –** Document Control

4.6 **BPR –** Batch Production Record

4.7 **FIFO –** First In, First Out; an inventory plan that ensures that items purchased first will be used first. Raw materials, components, drug related products, containers, and closures approved for use shall be rotated so that the oldest approved stock is used first (deviation from this requirement is permitted if such deviation is temporary and appropriate)

4.8 **SAP** – Enterprise Resource Planning; software which supports automation and processes and manages day-to-day business activities such as accounting, procurement, project management, risk management and compliance, and supply chain operations

4.9 **WMS** – Warehouse Management System; software which controls and administers warehouse operations from the time goods or materials enter the warehouse until they move out

5.0 References

5.1 F-505, SOP, Environmental Monitoring Program

5.2 D-303, SOP, Recertification of Expired Raw Materials

5.3 QS-106, SOP, Allergen Control

5.4 21 CFR § 111.415(f)

6.0 Procedure

Note: Only Warehouse personnel are to receive, pull, and restock inventory items.

6.1 Annual Inventory

6.1.1 The annual inventory stock count is represented as our annual fiscal year cycle count program. The cycle count program methodology implemented captures all warehouse locations with stock on hand to be counted twice per year. Inventory will be documented systemically via inventory counting transactions in SAP and reviewed by Finance.

6.1.2 If any discrepancies are discovered during the verification of cycle count program inventory records, production management and inventory control must be informed to investigate the variance(s).

6.1.3 Inventory of Allergens, Gluten, Non-GMO Project Verified, Certified Organic, Kosher, and Halal- related materials will be done in their respective designated areas of the warehouse. Care is used to not move materials out of the designated areas to ensure there is no chance for cross-contamination.

6.2 Electronic Documentation

6.2.1 The electronic documentation system (SAP/WMS) is the system in which employees can determine the current status of inventory items.

6.2.2 Only Warehouse employees, Production leadership, Purchasing staff, and Accounting staff have authorization to make changes in the inventory system.

6.2.3 It is the responsibility of Inventory Control and Warehouse personnel to ensure that the inventory system is current at all times of operation.

6.2.4 The inventory system is used to keep an inventory of the following items:

6.2.4.1 Raw Materials (solids, semi-solids, liquids)

6.2.4.2 Capsules (empty)

6.2.4.3 Caps and Closure Systems

6.2.4.4 Bottles and Containers

6.2.4.5 Packaging Supplies

6.2.4.6 Printed Packaging Components (labels, shrink sleeves, cartons, display trays, etc.)

6.2.4.7 Corrugated Boxes

6.2.4.8 Customer Supplies Raw Materials

6.2.4.9 Customer Supplied Packaging Supplies (when applicable)

6.2.5 All of the items are to be documented in the system and kept up to date as they are added, removed, sampled, or destroyed.

6.2.6 The electronic documentation system is for reference only.

6.3 Storage

6.3.1 Storage of all raw materials and packaging components follow SOP F-505 Environmental Monitoring Program for the storage conditions of inventory.

6.3.2 Material and components will be stored in a FIFO manner.

6.3.3 Raw material liquids will only be stored in the same locator (ground level and second locator only) with like-liquid raw materials.

6.3.4 All allergen-related material is received and immediately placed in a designated allergen area. Allergen-related material will be stored with like-material in a

designated area as required by SOP QS-106 Allergen Control.

6.3.5 All Gluten, Non-GMO Project Verified, Certified Organic, Kosher, and Halal-related material is received and immediately placed in a designated area and stored with like-material if applicable.

6.3.6 Raw materials that are stored in the limited access storage area will be stored in segregated, designated areas and maintained by Warehouse/Production Management. Each area will be identified by proper signage.

6.3.7 Non-human consumption raw materials will be stored in separate designated areas and properly identified.

6.3.8 Expired raw material will be held in a designated quarantined area. Refer to SOP D-303 Recertification of Expired Raw Materials.

6.4 Allocation – Raw Material Pulling

6.4.1 Using FIFO, warehouse personnel will be responsible for pulling all raw materials used during the mixing process.

6.4.2 Allergen, Certified Organic, Halal, and Kosher raw materials will be identified by the BPR and associated product labeling.

6.4.3 Warehouse personnel use the production schedule to pull batches based on priorities set by Warehouse Management / Production Control Management.

6.4.4 Check for accuracy of materials by verifying the product name # as indicated in the BPR.

6.4.5 In weighing and dispensing, personnel will start the steps to weigh the materials, following the instructions in the BPR. The quantities used will be properly recorded in the space provided in the BPR.

6.4.6 At the end of the batch run, the operator will document the quantity of the materials used in the batch record. Inventory Control team will receive inventory from the electronic inventory system.

6.4.7 Weighing and Dispensing operators will return the raw materials to the staging area and ensure that the partial material has been closed and resealed on each container then placed into another plastic bag (secondary confinement) to protect content integrity. Additionally partial containers will be identified by means of sealing up with yellow tape and a yellow return label will be placed on the material. All material must be properly identified with the original R#, RMID, and weight.

6.4.8 Warehouse personnel will restock the raw materials to the appropriate locations.

6.5 Allocation – Packaging Component and Printed Packaging Pulling

6.5.1 Using FIFO, warehouse personnel will be responsible for pulling the packaging components for each job in packaging.

6.5.2 Warehouse personnel stages materials based on the priorities from the production schedule, Warehouse Manager or Production Director.

6.5.3 Warehouse personnel will ensure that partial boxes of packaging components are pulled to be used first.

6.5.4 In packaging, the material's R# will be documented in the packaging section of the BPR by Packaging personnel.

6.5.5 At the end of the batch run, the operator will document the quantity of the materials used in the BPR.

6.5.6 Packaging operators will return the components to the warehouse. Warehouse will restock the materials.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	07/23/10	New	-	-
1	05/17/13	Changed SOP format and number. Updated SOP.	-	-
2	09/27/13	Added additional requirements to sections 5.4.1 and 5.5.1.	13-832	B. Mosall
3	03/13/14	Added section for proper confinement of partial or open material.	14-0182	L. Titolo
4	04/21/14	Added requirements for allergens	14-0341	S. Millar
5	10/18/17	Complete rewrite to update to current process.	17-1296	S. Millar
6	04/30/18	Added storage requirements for liquid raw materials.	18-0149	S. Millar
7	10/01/20	Procedure rewrite to incorporate label control warehousing	CC-20-0697	J. Murphy
8	04/29/21	Added references to Non GMO Project Verified and Organic materials	CC-21-0176	C. Mitchell
9	07/02/21	Added certified to organic references. Added CFR 111.415(f) to section 5.0. Added Halal and Kosher references. Revised annual inventory procedure.	CC-21-0256	R. Pagano
10	11/09/21	Added Halal and Kosher to section 6.3.5	CC-21-0423	C. Mitchell
11	05/16/22	Added note in section 6.4.7 to use yellow tape and a yellow return label when returning partial cases back to the warehouse.	CC-22-0228	J. Murphy
12	03/16/23	Remove SOP B-901 reference. Add QS-106 reference. Update allergen and special material storage requirements. Change blending to weighing and dispensing. Add additional definitions. Update format, wording, and clarifications throughout.	CC-23-0134	J. Murphy
13	08/15/23	Add Gluten to 6.1.3 and 6.3.5	CC-23-0416	C. Horelle