1. PURPOSE:
   1.1. To establish a written procedure for lot traceability throughout receipt, manufacturing, packaging, and shipping.

2. SCOPE:
   2.1. These written requirements apply to receiving, manufacturing, and packaging.

3. RESPONSIBILITY:
   3.1. The warehouse personnel are responsible to receive in the proper material with the appropriate receipt with material identification and lot numbers from the suppliers.
   3.2. The pharmacy personnel are responsible to ensure the correct input of lot numbers are transcribed into the batch records which reflects the lot numbers that are received on the raw ingredient labels.
   3.3. Quality unit is responsible to ensure that the lot numbers are correctly transcribed and written in the batch record. Quality Unit consists of Quality Assurance and Quality Control.
   3.4. The packaging department as well as QA is responsible to correctly input the proper lot numbering on the product and correctly transcribed in the batch record.

4. DEFINITIONS:
   4.1. Lot traceability: is a "lot" of products that were made together in the same production run and produced using the same materials**.** Traceability allows manufacturers to track products throughout the supply chain. This is done by assigning identification labels to each production run which can then be tracked.
   4.2. Product traceability allows for complete and up to date histories of all batches of products from the starting materials to the complete final product. Identification and status of materials is provided by unique and controlled numbering system. The system (spreadsheets/system) can be interrogated to provide reports to allow for full traceability.

5. PROCEDURE:
   5.1. Receipt of materials
      5.1.1. Raw Ingredients are identified at the time of receipt.
      5.1.2. Each raw ingredient has a unique identifying number. (ANNEX 1)
      5.1.3. At the time of receipt each material shipment is given a unique lot number from the supplier.
      5.1.4. The inventory (spreadsheets/system) are maintained by personnel inputs and upon the reviewing of this information. (Inputs and Outputs)
   5.2. QA Approval of Materials
      5.2.1. Quality Laboratory approves, the raw ingredients verifying the lot number and RI Number.
         5.2.1.1. The Quality unit also approves the components and labels.
      5.2.2. When approved by QA, a green approval sticker is given along with an inventory stock card to the warehouse. (ANNEX 2) Traceability begins during storing and issuing materials.
   5.3. Manufacturing Products
      5.3.1. All products that are manufactured have two sets of numbers that identify the batch number and the product code.

5.3.2. Products are assigned a controlled number. The lot numbering system is as follows for batches are A 23 C 001:
- 5.3.2.1. A=AVIVA
- 5.3.2.2. 23=year
- 5.3.2.3. C=Month
- 5.3.2.4. 001= sequential batches/lots made starting with the number one.

5.3.3. A product code is given at the time when a Sales Order is received. The product code does not change.
- 5.3.3.1. If a change was made by the customer as per formulation, the product code would change to the next available sequential number.

5.3.4. The unique production batch number and lot number is used to trace all processing steps.

5.3.5. Product traceability is progressively recorded in the manufacturing batch record throughout manufacturing. (ANNEX 3 and ANNEX 4).

5.4. Processes

5.4.1. Full traceability is assured through issuing appropriate documentation and maintaining records that accompany every step upon receipt through batch manufacturing and packaging, onto shipping the product.

5.4.2. All components, raw Ingredients, and finished products undergo inspection and testing at various stages of their processing to verify their adherence to standards which is detailed in relevant documentation.

5.4.3. Only authorized warehouse person will receive the incoming goods and sign/date on the goods receipt. Reference (SOP WH-006 RM-PM Code Numbering).

5.4.4. Upon completion of every inspection and test procedure, results are given to attest that the item is allowed to proceed to the next stage in its processing.

5.4.5. Authorized dispensary personnel will sample the raw ingredient to the laboratory for testing. (SOP-WH-002) Sampling Handling.

5.4.6. Authorized dispensary personnel will dispense the raw ingredient to the Pharmacy according to the batch record. (SOP-WH-004) (ANNEX 3)

5.4.7. The change in status of the product/batch can be marked in various ways as in Authorized persons signature and date on the forms and batch records.

5.4.8. Authorized production personnel will request on a receipt document. (SOP-WH-008) Inventory Stock Card)

5.4.9. Authorized laboratory personnel will test the raw ingredient according to the approved specification and Test Reports. (SOP-QC -002 Testing of RM and FP)
- 5.4.9.1. Product identification is noted on the Certificate of Analysis at testing.
- 5.4.9.2. Product Batch/Lot number is noted on the Certificate of Analysis

5.4.10. The product code, batch number are in combination for traceability for distribution, recall and destruction of all finished products.

5.4.11. Individual sell units of dietary supplements, as well as product cases are labeled with unique lot numbers for proper management and traceability of production lots. The individual package codes and product case codes are to be the same.

6. REFERENCES: 21 CFR 111.160 (d)

7. REVISION HISTORY

| Revision | Changes |
|---|---|
| 01 | Original |

8. ANNEX 1 Raw Ingredient Identification Label used on the Raw ingredients upon incoming of the raw ingredient. (Example).

**AVIVA**

**RI:**

**Item:**
**Lot #:**
**Expiry Date:**
**Net Weight:**
**Date Received:**

9. ANNEX 2 Raw Ingredient identification label upon QA Release (Example).

Aviva - RELEASED

RM ID# :RI1084
Product: Unstain Turmeric Blend
Lot: PD032
Exp Date: 01/2023
Weight (KG): 25Kg
By: MP

10. ANNEX 3 Identification Label used in the pharmacy department to show Product Name, Product Code, Lot#, Raw Material description and the raw material Number (Example).

| IN PROCESS FOR PHARMACY | | | | |
|---|---|---|---|---|
| CONTENTS THIS CARTON | | | POWDER | |
| PRODUCT # | B1173 | LOT # | A23C001 | |
| PRODUCT NAME | Vita Chic Myoinositol Veggie Capsules | | | |
| RAW MATERIAL | Nuflow ™ | | | |
| RAW MATERIAL ITEM NUMBER | RI0222 | | | |
| WEIGHT (KG) | 0.54 | | DATE: | 3/1/2023 |

11. ANNEX 3 Capsule Label to allocate the capsules for a product going into manufacturing with the product lot number. (Example).

**B1173**
**A23C001**

12. ANNEX 4 In process label used when manufacturing capsules. (Example of encapsulation)

| IN PROCESS FOR ENCAPSULATION | | | |
|---|---|---|---|
| BLEND GOOD UPTO | | | 4/30/2023 |
| CONTENTS THIS CARTON | | | POWDER |
| PRODUCT # | B1173 | LOT # | A23C001 |
| PRODUCT NAME | Vita Chic Myolnositol Veggie Capsules | | |
| NET WT (kg): | | Blender Used: | |
| OPERATOR: | | DATE: | |