VitaCare Pharma

SOP #	VC-NPR-008	TITLE:	Effective:	11/16/12
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REVIEWED BY/DATE:	QUALITY APPROVAL/DATE:
Patel 10/11/23	10/11/23

1. **Purpose:**
   To describe a general outlines to hold and distribute nutritional and dietary supplements

2. **Scope:**
   This SOP applies to all raw materials/components (packaging/labels) and products either received or manufactured by VitaCare Pharma. The goal is proper holding and distributing raw materials, components and dietary products (in-process or finished) under appropriate temperature, humidity and light so that the identity, purity, strength and composition of the components and dietary supplements are not affected and that there are no mix ups and/or cross-contamination.

3. **Responsibility:** Warehouse Personnel, Production Manager, Quality Assurance

4. **Reference:** 21 CFR 111 Subpart M 111.455; 111.460; 111.470; 111.475 (b)(1)

5. **Procedure:**
   a. Warehouse personnel should ensure that all components and raw material under quality control check are kept in designated "QUARANTINE AREA" until further notice.
   b. Warehouse personnel should ensure that all raw materials, any components and products released by quality control are kept in designated **"RELEASED AREA".**
   c. Any allergen raw materials received by Warehouse personnel must follow SOP # VC –NQA-033 for storage requirements.
   d. Warehouse personnel also ensure that all in-process products are kept in designated "IN-PROCESS STAGING AREA".
   e. Warehouse personnel has to ensure that raw materials, in-process or finished products and any components rejected by quality control are kept in designated **"REJECTED AREA"** and cannot move to any other area until further notice.
   f. All raw materials, dietary supplements, packaging materials are properly labeled with all the necessary information for easy identification that prevents mix-up, contamination or deterioration of components/in-process materials/dietary supplements and packaging materials.
   g. Warehouse personnel will keep warehouse area in a clean and sanitary condition at all times. Please refer SOP-VC-NPR-003.
   h. Warehouse and production area are kept and monitored under recommended temperature and humidity control all time. Please refer SOP-VC-NQA-017.
   i. If there is any spill or damaged container, immediately clean or replace the container.
   j. Maximum of two raw materials or in-process or finished products are allowed to be stacked on the pallet with proper labels, such as **"MIXED LOTS" or "MIXED PRODUCTS",** etc.

k. If any raw material which is heat sensitive and is required to be stored under special conditions, such as in refrigerator or freezer; store material as recommended storage condition.
l. A NIST certified thermometer or temperature recording device shall be placed in the refrigerator or freezer to monitor and to record the temperature, to ensure the material is being stored under the recommended storage condition.
m. Thermometer or temperature recording device shall be calibrated periodically as per calibration certificate to obtain accurate and precise results. Please refer SOP-VC-NQA-008.
n. While distributing or shipping any components or dietary products, warehouse personnel will ensure that the cleanliness and sanitary condition of the transporting carrier are satisfactory, before transporting to other facilities, so that it will protect the dietary supplements against the contamination and deterioration. Please refer SOP-VC-NPR-009.
o. In-process and shipping flow are closely followed and monitored by Production Manager.

6. Archiving SOP:

All original documents are to be archived by QA & controlled copies are to be submitted to concerned departments.

7. Revision History:

Rev. No.	Revision Details	Reference/CCF No.	Effective Date:
00	New Procedure	N/A	11/16/12
00	Periodic Review	SOP # VC-GEN-001	06/23/16
00	Periodic Review	SOP # VC-GEN-001	10/11/18
00	Periodic Review	SOP # VC-GEN-001	10/11/21
00	Periodic Review	SOP # VC-GEN-001	10/11/23