



VitaCare Pharma

ORIGINAL

SOP #	VC-NPR-005	TITLE:	Effective:	11/15/12
Revision #	00	Cleaning and Storage of Utensils used for Production	Status:	APPROVED
Superseded By:	N/A		Total Pages:	02

REVIEWED BY/DATE:	QUALITY APPROVAL/DATE:
<i>Platel 10/18/21</i>	<i>megsual 10/18/21</i>

1. Purpose:

To describe a general, cleaning and storage procedure for all type of utensils used in the manufacturing of a batch of dietary supplements.

1. Scope:

This SOP applies to various type of the utensils used at various manufacturing stages of a batch of dietary supplement. Utensils, such as pots, pans scoops, spatula, bowls and other small containers/items are used for holding or mixing materials, blends, in-process batches or even packaging of the finished products.

3. Responsibility: Production Operators/Supervisor, Quality Assurance

4. Reference: 21 CFR 111 Subpart D 111.27 (a)(1) (2) (3) (4), (d)

5. Procedure:

- a. Remove all utensils used in manufacturing operation from the production room at the end of the process, and moved to the designated "Cleaning Area".
- b. Wash them with warm tap water until all visual residues are removed.
- c. Clean with Alconox® or use cleaning soap as a detergent in a 1% dilution (Take 50 grams of the powder in a 5 liter of warm water). If required, use scrubbing brush to remove sticky materials.
- d. Finally, rinse with warm tap water or purified water until no foam is observed.
- e. Allow to air dry and then cover each utensils with a clean polyethylene bag. Secure with either twist tie or knob and store in the designated "Clean Staging Area".
- f. Wipe it out the utensils with a clean lint free cloth soaked in isopropyl alcohol before use.
- g. Never put any cleaned utensils on the bare floor as they might get contaminated.
- h. Re-clean any utensils that are soiled or contaminated during the processing of a batch.
- i. Following general measures should be taken for equipments and utensils to protect components and dietary supplements from getting contaminated from any source.
 - If tools must be used on equipment during production then the tools should be clean, so as to prevent cross contamination. Tools are not to be stored on top of equipment, ledges or electrical boxes but should be stored in cabinets, tool box or outside of product contact areas.
 - Storage of cleaned equipment and utensils shall preclude adulteration from other activities in the area, or airborne contamination.



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- Utensils for cleaning, or for product contact shall have specific, convenient and sanitary storage hangers or shelves. Items shall not be stored on the floor, pallets or against painted surfaces.
- Mops are not to be stored in water but hung up to dry after use.
- Water or air hoses shall be stored off the floor.
- Brooms should not be a source of contamination, and should be only used in the areas, designated for its use.
- Facilities and/or equipment and utensils shall be designed to prevent product or product contact surfaces from coming in contact with non-product contact areas such as floors and walls.
- Bulk unloads hose systems shall be labeled, capped and secured, if used.
- Ancillary piping should be labeled as to contents to prevent wrong connections.
- Equipment welds and seams shall be polished and smooth, to prevent accumulation, and facilitate cleaning.
- Equipment and utensil surfaces are inspected at routine intervals for signs of wear, damage, rusting, rouging (in stainless steel equipment), pitting or gouging, stains, cleanliness, etc. Interior surfaces should be clean, smooth (seamless) and in good condition.
- Equipment such as freezers, refrigerators, etc. that are used to hold components or dietary supplements must be functioning properly and adequately designed.

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	11/15/12
00	Periodic Review	SOP # VC-GEN-001	06/22/16
00	Periodic Review	SOP # VC-GEN-001	10/18/18
00	Periodic Review	SOP # VC-GEN-001	10/18/21