
 MBI NUTRACEUTICALS	STANDARD OPERATING PROCEDURE CONFIDENTIAL		SOP NUMBER/RELEASE FA-001 / 5
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SOP COVER PAGE

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1. PURPOSE

- 1.1. This Standard Operating Procedure (SOP) defines requirements for building and facilities maintenance.

2. SCOPE

- 2.1. This Good Manufacturing Practices (GMP) SOP addresses the premises, including the design and construction of building(s) used for storing MBI Nutraceuticals products. This SOP includes suitable environmental conditions, good sanitary practices, minimization of extraneous material migration, and rodent/pest control. See Equipment SOPs for cleaning and maintenance of specific equipment.

3. RESPONSIBILITIES

- 3.1. All GMP personnel are required to maintain their respective areas according to the procedures in this SOP.
- 3.2. Sanitation personnel are responsible for performing the tasks in the cleaning logbooks according to the procedures in this SOP.

4. REFERENCES

- 4.1. FA-008 Environmental Monitoring
- 4.2. EQ-006 General Equipment Cleaning

5. MATERIALS AND EQUIPMENT


- 5.1. Refer to SOP FA-002 for cleaning solutions suitable for mopping and wiping down various equipment or other surfaces.

6. SAFETY REQUIREMENTS


- 6.1. All cleaning products are to be used according to label directions.
- 6.2. Use appropriate personal protective equipment.

7. PROCEDURE

- 7.1. Regular maintenance is required to prevent deterioration of the premises. For example, holes in walls and floors should be repaired as soon as possible; worn surfaces or those with chipping paint should be repainted, etc.
- 7.2. The warehouse shall be maintained below 77°F to maintain stability of MBI Nutraceuticals products (see FA-008 Environmental Monitoring).
- 7.3. Production areas are to be segregated from non-production areas.
- 7.4. The water system shall be monitored by an electrical monitoring system and associated water tanks shall be changed as needed to maintain the efficacy of the system. (See SOP FA-003 Water System Maintenance).
- 7.5. Cleaning procedures
 - 7.5.1. Approved Cleaners
 - 7.5.1.1. Waxie 320
 - 7.5.1.1.1. Bathroom surfaces
 - 7.5.1.2. Waxie 543
 - 7.5.1.2.1. Glass and surfaces

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- 7.5.1.3. Waxie 910
 - 7.5.1.3.1. No Rinse Sanitizer
- 7.5.1.4. Waxie BRK AWAY
 - 7.5.1.4.1. Fats, grease, oil, soil
- 7.5.1.5. CureCrete Crete Clean
 - 7.5.1.5.1. Floors and Concrete
- 7.5.1.6. Bleach
 - 7.5.1.6.1. Pouring down drains
- 7.5.1.7. Dawn Dishwashing Liquid
 - 7.5.1.7.1. Washing dishes and equipment
- 7.5.2. General warehouse
 - 7.5.2.1. Sweep and mop floors.
 - 7.5.2.2. Vacuum shelves and clean.
 - 7.5.2.3. Periodically inspect items on pallets to evaluate cleanliness. If dust has accumulated, clean the exterior of the pallet by blowing with compressed air, wiping with a damp rag, or other suitable method.
- 7.5.3. Production areas including encapsulating, tableting, and dry mixing rooms
 - 7.5.3.1. Clean the outside of machines.
 - 7.5.3.2. Sweep and mop floors.
 - 7.5.3.3. Clean plastic drapes
- 7.5.4. Wet mixing area
 - 7.5.4.1. Clean walls.
 - 7.5.4.2. Clean the inside of storage cabinets by wiping the shelves and sides around the components.
 - 7.5.4.3. Clean utensils, pails, and other containers according to procedures described in SOP EQ-006 General Equipment Cleaning.
- 7.5.5. Storage areas for raw materials, packaging, and finished products
 - 7.5.5.1. Vacuum and wipe down shelves.
 - 7.5.5.2. Clean items on the shelves of dust and debris.
- 7.5.6. Offices and bathrooms
 - 7.5.6.1. Sweep and mop floors.
 - 7.5.6.2. Wipe down sinks and toilets with Waxie 320 solution.
 - 7.5.6.3. Wipe down shelving and walls.
 - 7.5.6.4. Replenish hand soap, paper towels, and toilet paper.
 - 7.5.6.5. Wipe dirty areas of walls, doors, and frames.

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7.5.6.6. Replace trash can liners.

7.5.7. Lunchroom

7.5.7.1. Wipe down all tables, chairs, and appliances.

7.5.7.2. Discard old food from the refrigerator.

7.5.7.3. Wipe down the inside of the refrigerator.

7.5.7.4. Replace trash can liners.

7.5.8. Packaging Area

7.5.8.1. Wipe down all packaging equipment on the line, including the tops of machines.

7.5.8.2. Turn on conveyor belts and wipe while circulating.

7.5.8.3. Wipe down shelves, boxes, and cartons.

7.5.8.4. After cleaning, cover exposed equipment with plastic to prevent contamination.

7.5.8.5. Sweep and mop floors.

7.5.9. Quality Control Laboratory

7.5.9.1. Clean laboratory benches.

7.5.9.2. Clean glassware.

7.5.9.3. Clean laboratory equipment exteriors.

7.6. Change mop and rinse water often for more effective cleaning. Discard cleaning water in toilets, not sinks, to prevent dirtying sink areas.

7.7. The premises shall be inspected and treated for pests by a licensed and certified contractor

7.7.1. Bait traps shall be inspected monthly, or as needed, by the contracted pest control providers.

7.7.2. Written records will be maintained for these services.


7.8. All doors leading to or from the outside must be kept closed at all times, other than during product shipping and receiving, or while entering or leaving the premises.

7.9. Restrooms must be well-ventilated and provide antibacterial hand soap and single-use towels.

7.10. An adequate number of garbage receptacles must be available in all areas.

8. RECORDS, REPORTS, AND FORMS

8.1. Cleaning logbooks

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9. HISTORY

RELEASE NO.	EFFECTIVE DATE	REASON/JUSTIFICATION FOR CHANGE
1	01/05/2006	New
2	01/08/2008	Minimum warehouse temperature lowered from 65 to 50 degrees.
3	09/20/2010	Updated SOP format with cover page, updated cleaning areas to match current premises.
4	05/29/2019	Updated personnel and references to other SOPs.
5	1/27/22	Elaborated on responsibilities, scope, references. Cleaners used.