
	MBI NUTRACEUTICALS	STANDARD OPERATING PROCEDURE CONFIDENTIAL	SOP NUMBER/RELEASE GP-021 / 2
TITLE: EMPLOYEE PRACTICES			PAGE NUMBER 1 of 5

SOP COVER PAGE

REVIEWED BY:	Signed: _____ Date: _____		
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APPROVED BY:	Signed: _____ Date: _____		
	Jeff Jensen, Vice President		
EFFECTIVE DATE:	2/20/2023	SUPERSEDES VERSION:	GP-021 Release 1 2/10/2020
If the SOP is reviewed and there are no changes (i.e. if it is not revised) then a signature and date (below) indicate the review has occurred. If a revision is required, a new version is released and the signature/date (below) do not need to be completed.			
Review Date:		Signature: _____	
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1. PURPOSE

- 1.1. This Standard Operating Procedure (SOP) describes employee practices for hygiene, dress, and procedures for protection against product contamination.

2. SCOPE

- 2.1. This procedure covers the minimum requirements for all employees with access to production, packaging, or storage areas to minimize risk of contamination to processes, ingredients, and finished products.

3. RESPONSIBILITIES


- 3.1. Management and Quality Assurance Personnel:
 - 3.1.1. Train and enforce the requirements of this SOP with all employees, contractors, or visitors who enter any production, packaging, or storage areas.
- 3.2. MBI Nutraceuticals employees, contractors, and visitors:
 - 3.2.1. Comply with the Good Manufacturing Practices described in this SOP.

4. REFERENCES


- 4.1. U.S. Department of Health and Human Services, FDA 21 CFR Part 211.28
- 4.2. U.S. Department of Health and Human Services, FDA 21 CFR Part 111
- 4.3. Centers for Disease Control Handwashing Protocol

5. PROCEDURE

- 5.1. Personal Hygiene
 - 5.1.1. Training on employee personal hygiene practices should be included in the mandatory annual cGMP training program. This training should cover basic knowledge of microbiological organisms and stress the employee's responsibility to protect product quality and safety through proper hygienic practices.
 - 5.1.2. Employees personal hygiene practices should include the following:
 - 5.1.2.1. Maintain personal cleanliness through regular bathing.
 - 5.1.2.2. Maintain oral hygiene through teeth brushing.
 - 5.1.2.3. Use deodorant or antiperspirant to avoid unpleasant body odors.
 - 5.1.2.4. Don't use heavily scented perfumes, colognes, or lotions that can cause allergic reactions, migraines, or respiratory problems for other employees.
 - 5.1.2.5. Maintain clean and trimmed fingernails.
 - 5.1.2.6. Wash hands after eating and using the restroom, see section 4.3 on hand washing.
- 5.2. Disease Control
 - 5.2.1. Any person (employee, visitor, or contractor) with an infectious or communicable illness, open lesions (including boils, sores, or infected wounds), or any abnormal source of microbial contamination, must be excluded from any operations that could result in product contamination.

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- 5.2.2. Instructions on reporting health conditions that could result in product contamination to supervisors should be included in the mandatory annual cGMP training program.
- 5.2.3. Health conditions that should be reported include, but are not limited to the following:
 - 5.2.3.1. Open lesions
 - 5.2.3.2. Boils
 - 5.2.3.3. Sores
 - 5.2.3.4. Infected wounds
 - 5.2.3.5. Fever
 - 5.2.3.6. Diarrhea
 - 5.2.3.7. Vomiting
- 5.2.4. When a supervisor learns or observes that an employee has a health condition that could threaten the safety of products, the supervisor must not permit that person to enter any production-related, packaging, or product storage areas.
- 5.2.5. Employees with such health conditions will not be permitted to enter any production-related, packaging, or product storage areas until the health condition no longer exists. Employees may be required to show written permission to return to work from a qualified medical expert.
- 5.3. Dress Code and Outer Garments
 - 5.3.1. Employees who handle component materials, finished products, or packaging or equipment that come in contact with products should wear white company-issued lab coats over street clothes.
 - 5.3.2. The lab coats should be designed to prevent foreign objects from falling into products and components. They should have snap-type closures, elastic sleeve cuffs, and no pockets above waist level. Employees should not clip pens, pencils, thermometers, phones, or other items on their garments above waist level.
 - 5.3.3. Lab coats should be maintained clean at all times. They should not be worn outside of the work area where there is a possibility of contamination. Lab coats should not be worn in parking lots, or anywhere outside of the production building.
 - 5.3.4. Lab coats should be removed before entering the toilet areas, cafeteria or break rooms. Storage locations are provided outside these areas for hanging outer garments.
 - 5.3.5. Lab coats are not to be taken home.
 - 5.3.6. Shorts and capri pants are not allowed in the warehouse, production, packaging, or laboratory areas. Only full length pants that cover the entire legs can be worn.
 - 5.3.7. Employees are issued dedicated shoes. These shoes are not to be worn outside or taken home. The inside of the entire plant is the controlled zone.
 - 5.3.8. All maintenance and warehouse employees should wear a lab coat while working in the plant. These employees also comply with dedicated shoe requirements. Shoe coverings are provided if short term outside use is needed.

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5.4. Hand Washing

- 5.4.1. All employees must wash their hands thoroughly using liquid soap and hot water before starting work, after breaks, after using restrooms, after leaving production areas, or whenever hands become contaminated.
- 5.4.2. Following is the Centers for Disease Control Handwashing Protocol:
 - 5.4.2.1. Wet your hands with clean, running water (warm or cold), turn off the tap, and apply soap.
 - 5.4.2.2. Lather your hands by rubbing them together with the soap. Lather the backs of your hands, between your fingers, and under your nails.
 - 5.4.2.3. Scrub your hands for at least 20 seconds. Need a timer? Hum the “Happy Birthday” song from beginning to end twice.
 - 5.4.2.4. Rinse your hands well under clean, running water.
 - 5.4.2.5. Dry your hands using a clean towel or air dry them.

5.5. Gloves

- 5.5.1. Gloves approved for food contact use should be worn by all employees who handle components, products, or equipment that contacts components or products.
- 5.5.2. Gloves must be kept clean and intact. Gloves should be replaced whenever they become damaged or contaminated.

5.6. Jewelry


- 5.6.1. Employees who work in production areas may not wear jewelry such as necklaces, chains, bracelets, watches, rings with stones, etc. Facial adornments such as appliques, stones, exposed body piercings, false fingernails, and fingernail polish are also forbidden.
- 5.6.2. Medical alert necklaces may be worn, if concealed and not removed while in production areas. Medical alert bracelets may interfere with proper handwashing and should be avoided.
- 5.6.3. Wearing one plain wedding band without a stone on the left ring finger is permitted, provided it is covered with an approved sanitary glove. Rings with stones are never permitted.
- 5.6.4. Visitors may wear a glove over a wedding ring that cannot be removed while in the warehouse.

5.7. Hair Restraints

- 5.7.1. Employees must wear company-issued hairnets in the warehouse, production, mixing, packaging, or any other areas where product-contact equipment are handled.
- 5.7.2. Hairnets must be worn over the ears in a manner that covers all hair. If necessary, two hairnets may be worn to cover all hair.
- 5.7.3. Caps, hats, and beanies must be covered with a hairnet.
- 5.7.4. All facial hair must be covered with a beard net or hairnet.

5.8. Personal Effects

- 5.8.1. Personal items such as coats, pocketbooks, bags, lunch boxes, food or drink items, etc. are not permitted in any production or packaging areas of the plant. Employees should leave these items in their lockers or in the locker room. Food and drinks are not allowed in personal lockers and should be stored in the lunchroom.
- 5.8.2. Nothing should be stored on top of lockers.

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- 5.8.3. Use of cosmetics and skin preparations are not allowed in the warehouse, production, or packaging areas.
- 5.8.4. Management may inspect all personal lockers.
- 5.9. Consumption of Food and Other Items
 - 5.9.1. Employees are not permitted to consume food, candy, or drinks (including water) in production and warehouse areas. The chewing of gum is also forbidden in these areas. Food and drinks must be consumed only in designated areas.
 - 5.9.2. The Hallway leading into the warehouse or into the GMP area has a designated water station shelf. All bottles/ containers must have a lid and spill proof. No open containers are allowed.
 - 5.9.3. Tobacco products, toothpicks, throat lozenges, and medicines are not allowed in production, packaging, and warehouse areas.

6. HISTORY

RELEASE NO.	EFFECTIVE DATE	REASON/JUSTIFICATION FOR CHANGE
1	02/10/2020	New
2	2/20/2023	Specific designated area for closed drink containers added to section 5.9.2