SOP COVER PAGE

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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.

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1. PURPOSE

1.1. This Standard Operating Procedure (SOP) describes the control of components and appropriate holding conditions to protect against mistakes, deterioration, and contamination.

2. SCOPE

2.1. This cGMP SOP includes control of goods received from external vendors, including raw materials, packaging materials, bulk products and finished packaged products.

3. RESPONSIBILITIES

3.1. Warehouse Employees

3.1.1. Receive components from outside vendors.

3.1.2. Perform truck inspections, initial quality check for received components, and final quality check for shipped products.

3.1.3. Control overall warehouse operations to assure product integrity.

3.1.4. Follow the procedures in this SOP for holding materials and components prior to release for use in finished products.

3.1.5. Complete all required documentation.

3.2. Quality Control (QC) Manager or designee

3.2.1. Performs qualification procedure for vendors that MBi receives products and components from.

3.2.2. Performs quality check on components, including identity for raw materials, and component confirmation for finished product where required

3.2.3. Reviews all COCs, COAs, and other quality control documentation.

4. DEFINITIONS

4.1. SDS- Safety Data Sheet

4.2. PPE- Personal Protective Equipment

4.3. COA- Certificate of Analysis

4.4. COC- Certificate of Conformance, or Certificate of Compliance

5. REFERENCES

5.1. U.S. Department of Health and Human Services, FDA 21 CFR Part 111

5.2. SOP QC-027 Raw Materials Sampling

5.3. SOP QC-031 Deviations and CAPAs

5.4. SOP QC-042 Allergen Control Program

5.5. SOP QC-043 Specifications

6. SAFETY REQUIREMENTS

6.1. When chemical exposure is possible, review SDSs periodically or for unfamiliar chemicals.

6.2. Use appropriate PPE, such as gloves, glasses/goggles, and lab coat.

6.3. In case of a spill, follow the cleanup procedure in the SDS.

7. PROCEDURE

7.1. Warehouse/Receiving

7.1.1. The warehouse manager or designee inspects all carrier trucks and rejects shipments when excessive dirtiness, pests, or damaged packaging are present.

7.1.2. Components that contain major food allergens should be identified, labeled, segregated, and documented as quickly as possible. See QC-042 Allergen Control Program.

7.1.3. When a raw material, packaging material, bulk product, and/or finished product arrives from an external vendor, the warehouse manager or designee initiates an entry in the electronic inventory database. Raw materials and packaging materials are also entered into a separate raw material database. Entries should be completed within two working days of arrival.

7.1.4. Storage conditions shall be at room temperature, unless otherwise indicated on the component packaging or other component documentation.

7.1.5. All packing slips, invoices, and other associated shipping-related paperwork are forwarded to the office manager for archiving.

7.1.6. If received with shipping paperwork, forward the COA or Certificate of Compliance for raw materials, packaging materials, bulk product, and/or packaged finished product to Quality Control for inclusion with other QC documentation.

7.1.7. Refer to SOP QC-027 for raw material sampling procedures.

7.1.8. Complete and affix a hold tag to each lot received. If multiple containers of the same lot are received, note on each container the receipt date and container number. The hold label must be placed on the outer shrink-wrap or similar barrier.

7.1.9. Received raw materials and components must be labeled with a “HOLD” tag and placed in a quarantine area while waiting for QC release. Once items have completed and passed QC specifications, the “HOLD” tag may be replaced with a “RELEASE” tag and the items may be moved to their appropriate storage location. Components must not be used prior to QC release.

7.2. Quality Control Testing and Release

7.2.1. When a sample is submitted to QC, the sample is tested, measured, or evaluated for quality according to an approved method. See QC-043 Specifications.

7.2.2. After testing is completed, the results are entered into the raw material database.

7.2.3. If the product passes QC criteria, the product is approved for release. If a product is rejected, the product is returned to the manufacturer.

7.2.4. To visually identify materials that are approved for release, a release tag is completed, initialed by QC, and applied over the hold tag on each lot. The material(s) may then be removed from the hold area.

7.2.5. If materials are used prior to release, a deviation must be documented per SOP QC-031, Deviations and CAPAs.

7.3. Warehouse and dock maintenance

7.3.1. Warehouse storage areas for raw materials, in-process products, finished products, packaging components, and labels must be adequate in size and kept clean and orderly at all times.

7.3.2. Allergens must be kept in a separate area from all other ingredients and components. Allergens must not be stored above other allergens or non-allergen components. For example, tree nut ingredients must not be stored above milk ingredients.

7.3.3. Vertical segregation should be maintained for components that are prone to leaking. In particular, liquid ingredients should not be stored above dry ingredients. Ingredients that come in single sacks are prone to getting holes and spilling. These components should preferably be stored below other components, or above more of the same components.

7.3.4. Warehouse and dock ceilings, walls, and floors must be in good condition, free from holes, cracks, or other damage.

7.3.5. Floors throughout the warehouse, under pallets, storage racks, aisles, and dock areas must be clean and free of dirt, spilled product, broken pallets, or debris of any type.

7.3.6. All exterior doors to product storage areas must be tight-fitting, with no evidence of light showing around the doors, to prevent the entrance of pests. It is recommended that exterior doors to product storage areas be equipped with functioning alarms.

7.3.7. Shipping docks, dock plates, dock levelers, and areas around and under the docks must be clean and free of accumulated debris, product waste, water, etc. These areas should be on the Master Sanitation Schedule.

7.3.8. Pallets, storage racks, and shelving must be kept clean and in good repair.

7.3.9. Adequate space must be provided between storage racks and warehouse walls to permit placement of rodent control devices and to facilitate inspections for pest activity.

7.3.10. Products must not be stacked so that blowers or vents are blocked, preventing the circulation of air.

7.4. Holding Raw Materials, In-Process and Finished Products

7.4.1. Ingredients, packaging components, in-process products, and finished products, must be effectively segregated from each other in the warehouse.

7.4.2. All containers, including those holding partially-used raw materials, must be kept tightly closed at all times to prevent contamination.

7.4.3. All containers must be properly labeled with the following information, at minimum:

7.4.3.1. The name of the material, product, or packaging component

7.4.3.2. ID number or code

7.4.3.3. Lot code

7.4.3.4. Weight (for ingredients, in-process, and finished products; not required for packaging components)

7.4.4. All containers must be held under appropriate temperature, humidity, and lighting conditions so that the identity, purity, strength, and composition of materials or products are not affected, and to prevent mold build-up on packaging components.

7.4.5. All containers must be stored off the floor, preferably on storage racks. A clearance of 6-inches is recommended. Standard pallets may be used.

7.4.6. Raw materials and product components must not be stored in close proximity to any chemicals including cleaners, pesticides, or other non-edible materials.

7.4.7. Damaged, leaking, or unsound containers must be immediately isolated and placed on hold for evaluation by QC. Item examination and disposal (if necessary) should be timely.

7.4.8. The inventory management system must strictly adhere to a FIFO stock rotation.

7.4.9. An area designated for holding retained, damaged, or non-conforming materials/components should be segregated. This area should be labeled “Quarantine Area”.

7.4.10. Only properly-packaged finished products in undamaged containers may be stored in and shipped from the warehouse. Products not cleared for shipment, or held for any other purpose, must be clearly identified and isolated in a designated area of the warehouse to prevent inadvertent shipment.

7.4.11. Partially-used or opened finished product containers are not permitted to be stored in the finished products storage area.

7.5. Holding of labels

7.5.1. Labels must be held under appropriate conditions of temperature and humidity, and in a manner that avoids confusion.

7.5.2. All pre-printed finished product labels and pre-printed packaging components must be securely stored in a locked cabinet or locked room with restricted access. Only authorized personnel may distribute finished product labels and pre-printed packaging.

7.5.3. Labels must be stored off the floor, preferably on shelves.

7.6. Refrigerated storage

7.6.1. Temperature-sensitive raw materials, in-process materials, and finished products must be stored at the proper temperature in areas of the warehouse that are refrigerated, or in refrigerators or freezers to minimize the effects of thermal degradation on products.

7.6.2. Refrigeration equipment used to store temperature-sensitive raw materials, in-process, and finished products, must be fitted with an accurate thermometer, temperature-measuring or -recording device, and have an automated device for regulating temperature, or an automatic alarm system to indicate a significant temperature change in a manual operation.

7.6.3. Thermometers, temperature measuring and recording devices on refrigeration units used to store temperature-sensitive materials and products, must be included in the equipment calibration program.

8. RECORDS, REPORTS, AND FORMS

8.1. Shipping/Receiving logs

8.2. Inventory database

8.3. Sample Dashboard

8.4. Laboratory Notebooks

8.5. SDSs

9. HISTORY

Release No.	Effective Date	Reason/Justification for Change
1	6/19/2019	New
2	1/27/22	Clarified hold/release procedure and responsibilities.
3	5/26/22	Combined QC-025 Control of Components with MF-006 Holding Manufacturing Components. Added procedure for vertical separation of allergens from each other and other components, not storing liquid components above other components.