1.0 Purpose

Warehouse facilities and areas used for holding in-coming raw materials and final product shall be designed and constructed to facilitate cleaning, maintenance and audited to minimize potential mix-ups or contamination. This procedure will cover the requirements of *21 CFR 211.142 and 150*.

2.0 Scope

cGMP practices in this procedure apply to all warehouses utilized be the company, to assure cleanliness of the facilities and prevent contamination or mix-ups during the lifecycle of the product.

3.0 Responsibility

It is the responsibility of all employees working to follow this policy.

4.0 Safety Considerations

Steel toed shoes and safety glasses are required at a minimum in all warehouse areas.

Safety is a condition of employment. Employees are not authorized to work in an unsafe manner and are prohibited from harming the environment or community.

5.0 Materials/Equipment

N/A

6.0 Policy

1. All warehouse areas shall be maintained in a clean and sanitary condition and in a proper state of repair. Buildings are sealed to minimize dust and dirt accumulation. Solid waste and trash are to be disposed of appropriately and not allowed to accumulate. Verification of daily and/or weekly cleaning shall be documented on the following forms:
   - *Repackaging Daily Cleaning Checklist (R13-FM-100-007)*
   - *RCF Cleaning and Maintaining Checklist (R13-FM-100-084)*
   - *Daily Duties Checklist (P12-FM-100-021)*
2. Bay doors to all warehouse facilities shall be controlled through restricted access, and maintained with screens to prevent contamination. Walk-through doors are secure, closed and locked at all times. *Good Manufacturing Practices (Q12-PL-100-003)*

3. Pest control policies are established to prevent access by pests, animals, or birds as outlined in *Pest Control (Q12-PR-100-009)*. Any insecticides, fungicides, fumigants, rodenticides, etc. have been approved for use in accordance with the U.S. Federal Insecticide, Fungicide and Rodenticide Act. Pest Control is provided by a licensed third party vendor.
4. Areas have been clearly defined and separated for quarantining of incoming raw materials, final product, non-conforming materials, and returned product; pending release or rejection by the Quality Unit utilizing the following procedures and placards:
   - *Nonconforming Material (Q12-PR-100-017)*
   - *Returned Product (Q12-PR-100-011)*
   - *Quality Hold (Q12-FM-100-002)*
   - *Quality Approved* (*Q13-FM-100-006)*
   - *Quality Rejected (Q13-FM-100-007)*
   - *Quality Unreleased (Q13-FM-100-008)*
5. All warehouse facilities are of appropriate conditions (temperature and humidity) for the temporary storage of incoming raw materials, packaging, and final product. Conditions are documented using the *Temperature and Humidity Log (R13-FM-100-052).* There is not a specified temperature and humidity range required to preserve the identity, quality, and purity of the product.
6. Warehouses will be maintained by following cGMP regulations that require the oldest inventory be distributed first, followed by inventory received more recently. The first products in are the first products to go out (FIFO). All products shall be easily traced in the event of a recall.
7. Various forms will be used to document auditing of the warehouses; including but not limited to the following forms
   - *Repackaging Safety and Housekeeping Weekly Audit (R12-FM-100-005)*
   - *Manufacturing Safety and Housekeeping Audit (Q13-FM-100-004)*
8. All supporting documentation will be maintained by the Quality Unit. *Document Retention (Q12-PR-100-005)*

7.0 Reference Documents

- *Repackaging Daily Cleaning Checklist (R13-FM-100-007)*

- *RCF Cleaning and Maintaining Checklist (R13-FM-100-084)*
- *Daily Duties Checklist (P12-FM-100-021)*
- *Good Manufacturing Practices (Q12-PL-100-003)*
- *Pest Control (Q12-PR-100-009)*
- *Nonconforming Material (Q12-PR-100-017)*
- *Returned Product (Q12-PR-100-011)*
- *Quality Hold (Q12-FM-100-002)*
- *Quality Approved* (*Q13-FM-100-006)*
- *Quality Rejected (Q13-FM-100-007)*
- *Quality Unreleased (Q13-FM-100-008)*
- *Temperature and Humidity Log (R13-FM-100-052)*
- *Repackaging Safety and Housekeeping Weekly Audit (R12-FM-100-005)*
- *Manufacturing Safety and Housekeeping Audit (Q13-FM-100-004)*
- *Document Retention (Q12-PR-100-005)*

8.0 Change Information

New Document