

| GILES CHEMICAL CORPORATION | | |
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| COMPANY PROCEDURE | | |
| Standard Operating Procedure | Page : 1 of 3 | Revision :12/20/2007 Date :01/24/2007 |
| Author: Stacy Howell | Title: Current Good Manufacturing Practices | |

Safety: The standard safety attire required for the area.

Purpose or Objective: The purpose of this procedure is to ensure that all employees have general knowledge of Current Good Manufacturing Practices (cGMP).

Giles Chemical Corporation is regulated by the Federal Drug Administration (FDA) as an over-the-counter drug therefore, is required to follow cGMP at all times.

Procedure:

Quality

- 1) Quality Manager and Associate approve or reject all product, packaging, and labeling of incoming, in-process and final product.
- 2) Quality Manager and Associate are responsible for maintaining adequate laboratory facilities.
 - Clean work environment.
 - Calibration of all lab equipment.
 - Documentation of all laboratory testing and outside contractors for lab calibration.

Personnel Qualifications

- 1) All Giles Chemical Corporation employees will receive continuous job specific training.
- 2) Giles Chemical Corporation will provide all shifts with adequate number of personnel to run the shift.

Personnel Responsibilities

- 1) All employees will wear protective clothing.
 - Giles Main plant is a closed system, therefore employees are not required to wear any protective clothing other than their uniform or safety equipment.
 - Giles repackaging facility is required to wear hairnets, smocks, gloves, and their usual safety attire when in production areas. **Employees should never touch product without wearing gloves.**
- 2) All Giles Chemical Corporation employees will follow good sanitation and health habits.
 - Employees will wash hands after visiting the restroom before returning to work.
 - Employees will wear clean clothing and maintain a clean personal appearance.

Maintenance

- 1) Maintenance is responsible for ensuring that all equipment is suitable for intended use.
- 2) Maintenance is responsible to ensure that all equipment is being properly cleaned and calibrated.

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- 3) Maintenance Manager must keep documentation of calibration and cleaning of all equipment.
- 4) Maintenance Manager is responsible for ensuring that all grease lubricants, etc... are food grade products.

Procedures

- 1) It is the responsibility of the Production Manager, Process Engineer, and Quality Manager to ensure that procedures are written so that employees can perform their job.
- 2) Quality Manager is responsible for ensuring that all procedures are placed on the documentation system. A hard copy of the procedure is filed in the office of the Quality Manager

Quality Hold

- 1) Giles Chemical Main plant employees and Management are responsible for holding any questionable material before release.
- 2) Material that is questionable must be tagged with a quality hold placard with a statement identifying a reason the material is being held and placed in the Quality Hold area. This area is designated in the warehouse of the Main Plant. Material can also be held in a bin, as long as the bin is clearly marked with Quality Hold tag and roped off with "DO NOT SHIP" tape. Giles Repackaging Facility must rope off material with "DO NOT SHIP TAPE" and place a Quality Hold placard stating a reason for the Hold on the material.
- 3) Quality Manager or Associate must be notified of the material on Hold. Quality Manager, Quality Associate, and Production Manager will review the material and make a decision on whether material can be shipped to another customer or must be discarded as a shipment.

Cleaning of Facility

- 1) Giles Chemical Corporation Main Plant and Repackaging Facility are responsible for maintaining a clean work environment for FDA regulations and safety of employees
- 2) Quality Manager, Maintenance Manager, and Production Manager are responsible for providing employees procedures on how to clean their area and equipment
- 3) Procedures will contain cleaning logs where employees must sign off specific items and areas in which cleaning has been performed.
- 4) Quality Manager and Quality Associate are responsible for doing weekly Safety/Housekeeping audits and posting it on the bulletin board.
- 5) Employees are responsible for signing off items that they have corrected and this list should be completed within a month from the assigned date.

Pest Control

- 1) Giles Chemical Corporation is required by FDA regulations to maintain pest control in their facilities.
- 2) Giles Main Plant and Repackaging facility controls pest through contract with Orkin
- 3) Orkin does quarterly inspections

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TRAINING DOCUMENTATION

| | EMPLOYEE | TITLE | SIGNATURE | DATE |
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