
	PREMIER MAGNESIA - GILES CHEMICAL			
	COMPANY PROCEDURE			
	Title: Current Good Manufacturing Practices	Page : 1 of 4	Revision : 03 Effective Date : 08/17/12	
Author: Stacy Lindsey		Procedure Number: QA-GMP		

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

cGMP training will be conducted upon hire and annually thereafter. Effectiveness will be assessed with a cGMP test. All documents will be maintained in QA cGMP binder.

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 employees will receive continuous job specific training.
- 2) Giles Chemical 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 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 Manager is responsible for the coordination of calibration of all equipment.

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- 3) Maintenance Manager is responsible for ensuring that all grease and lubricants that comes in contact with finished product is food grade. Giles Main Plant uses food grade grease in areas that

have the potential to come in contact with product. Giles Repack Facility uses food grade grease in all areas of production.

Procedures


- 1) It is the responsibility of the Maintenance Manager, Plant Manager, Production Manager, Process Engineer, Director of Operations, 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 Main Plant and Repackaging Facility are responsible for maintaining a clean work environment for FDA regulations and safety of employees.
- 2) Giles Chemical Plant Manager is responsible for cleaning of all production equipment.
- 3) Giles Plant Manager is responsible for providing clean logs to Quality Department for filing.
- 4) Maintenance is responsible for clean-up of their area after service of equipment.
- 5) Quality Manager, Maintenance Manager, and Plant Manager are responsible for providing employees procedures on how to clean their area and equipment
- 6) Procedures will contain cleaning logs where employees must sign off specific items and areas in which cleaning has been performed.
- 7) Production Management along with Operators are responsible for doing weekly Safety/Housekeeping audits and posting it on the bulletin board. Employees are responsible for signing off items that they have corrected and this list should be completed within a month from the assigned date.

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Pest Control

- 1) Giles Chemical is required by FDA regulations to maintain pest control in their facilities.
- 2) Giles Main Plant and Repackaging facility controls pest through a contract with Licensed Pest Management.
- 3) Licensed Pest Management Contractor performs monthly inspections and bi-monthly spider spray.

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Revision Number	Revision Date	Effective Date	Revision Author	Quality Approval	Production Approval	Revision Description
00	12/20/07	12/20/07	Stacy Lindsey			New Document
01	01/24/07	01/24/07	Stacy Lindsey			-Changed Terminex to Orkin
02	12/08/09	12/08/09	Stacy Lindsey			-Changed Teminex to Licensed Pest Management -Changed Cleaning responsibilities to Plant Manager -Modified Cleaning of Facility section
03	08/17/12	08/17/12	Stephen Ballew	Deborah Durbin	Jason Bumgarner	-3 year revision -Placed on new form -Added line about training schedule and document maintenance