
	GILES CHEMICAL ~ PREMIER MAGNESIA		
	Company Procedure		
	Title: Reserve Samples - Manufacturing	Number: L13-PR-100-042	
	Owner: Deborah Durbin	Revision: 1	
	Effective Date: 04/23/14	Page: 1 of 3	

1.0 Purpose

The purpose of this procedure is to describe how to appropriately identify, collect, label, and store a reserve sample that is representative of each manufactured Lot. Retention of reserve samples is for the purpose of potential future evaluation of the quality of manufactured Lots and not for future stability testing purposes.

2.0 Scope

This procedure applies to weekly and daily reserve samples of magnesium sulfate heptahydrate produced at the Manufacturing facility.

3.0 Responsibility

Quality Associate – is responsible for following this procedure.

4.0 Safety Considerations

PPE required at Manufacturing includes steel-toed shoes and safety glasses.

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

5.0 Materials/Equipment



- Clean, unused, 6"x8", 2 mil, plastic zip-top bag
- Sharpie
- Salt Sample Collection Utensil

6.0 Procedure

Reserve samples are only required (21 CFR 211.170) to be collected and retained for each manufactured Lot (weekly). However, reserve samples are also collected daily for the purpose of monitoring any daily changes with physical characteristics such as color or crystal size.

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Collection:

- Obtain a clean, unused, 6"x8", 2 mil, plastic zip-top bag from the QA Lab. Using a Sharpie, clearly label the bag with the following information:
 - daily affirmation Lot number (which includes the weekly Lot number)
 - date sample is being collected
 - initials of the person collecting the sample

The bag used to store reserve samples should have properties equivalent to or more protective than the marketed packaging system.

- Collect the reserve sample daily from the sample port located on the dryer chute. Following procedure L13-PR-100-061, *Salt Sample Collection Utensil*, use the designated sampling utensil to insert into the port and fill with free flowing salt. Place the handle of the spoon inside the opening of the sample bag and pour the salt into the bag. Clean, dry and properly store spoon after use.

Sufficient quantities should be retained to conduct at least two full compendial analyses or, twice the quantity necessary to perform any other required tests. Specified sample bag contains approximately 1-2 pounds of product; more than a sufficient quantity.

Documentation:



- Return the reserve sample to the QA Lab and log collection information onto the *Daily Reserve Sample Log (L13-PR-100-F042)*.
- *Daily Reserve Sample Log* or any other supporting documentation is filed in the cGMP Library for a period of at least 4 years.

Retention Location:

- Reserve samples shall be retained and stored in the QA storage area as space permits and then transferred to an off-site storage facility for the remainder of the appropriate retention time. These storage conditions are consistent with product labeling.

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Retention Time:

- Reserve samples representative of each weekly Lot are retained for at least one year after the expiry date of the specific Lot or for 4 years.
- Reserve samples representative of daily affirmation Lots are retained for at least one month from the collection date of the sample.

7.0 Reference Documents

Daily Reserve Sample Log (L13-PR-100-F042)
Salt Sample Collection Utensil (L13-PR-100-061)

8.0 Change Information

Reviewed and updated document with new sampling port location.

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