
	GILES CHEMICAL ~ PREMIER MAGNESIA		
	Company Procedure		
	Title: Smart2Pure Water System Maintenance	Number: L15-PR-100-065	
	Owner: Hunter Douglas	Revision: 0	
	Effective Date: 7/22/2015	Page: 1 of 2	

1.0 Purpose:

The purpose of this procedure is to establish a maintenance program for the Thermo Scientific Smart2Pure water system located in the manufacturing quality lab. This procedure will help to insure compliance with 21 CFR 211.67 'Equipment Cleaning and Maintenance'.

2.0 Scope:

This procedure applies to the Thermo Scientific Smart2Pure water system (S/N: 41790078) and will be performed at the intervals specified within this SOP or any time a drop in performance is noted.

3.0 Responsibility:

Quality Assurance Lab personnel or designee is responsible for performing this procedure.

4.0 Safety Considerations:

Appropriate PPE should be worn at all times including but not limited to steel-toed shoes, gloves (nitrile or latex), safety glasses, and a lab coat.

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:

- ICP-OES equipped to analyze for inorganic elements
- Spectrophotometer w/ ability to analyze TOC
- TOC analysis Kit
- Pretreatment cartridge (Art. # - 09.2003/09.2006) (if needed)
- Filter cartridge (Art. # - 09.1020) (if needed)
- Sterile filter capsule (Art. # - 09.1003) (if needed)
- Paper Towels
- Ultra Pure Water



6.0 Procedure:

Monthly-

- Wipe down the unit with a clean damp cloth or paper towel.
- Clean below the unit and check for any spills or leaks.
- Document cleaning on *Maintenance Log (L15-FM-100-019)*

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Every 6 Months-

- Perform the monthly cleaning as listed above.
- Perform a TOC analysis on the water produced to verify the water is free of organic compounds (< 10 ppm) using Ultra Pure water as a blank.
- Perform an ICP analysis on the water produced to verify the water is free of metals (< 10ppm) that are of interest in USP Monograph for Magnesium Sulfate (As, Cd, Hg, Pb, Cu, Fe, Ni, Se, and Cl).
- Document cleaning on *Maintenance Log (L15-FM-100-019)*

Annual Maintenance-

- Perform the monthly cleaning as listed above.
- Replace consumable items (cartridges and filters).
- Discard the first 6L of water that the unit produces.
- Analyze the water produced on the ICP and the Spectrophotometer as listed above.
- Document cleaning on *Maintenance Log (L15-FM-100-019)*

Notes-

- TOC analysis will be performed using Ultra Pure water as a blank.
- If water should fail TOC or ICP metals testing, the filters should be replaced and the product should be rerun.
- If rerun should fail, the unit must be tagged out and serviced.

7.0 Reference Documents:

Maintenance Log (L15-FM-100-019)

8.0 Change Information:

New Document

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