

**GILES CHEMICAL ~ PREMIER MAGNESIA****Validation Protocol**

Title: Stability Oven IQ/OQ Protocol

Number: L17-VAL-100-067

Owner: Ashley Williams

Revision: 0

Effective Date: January 16<sup>th</sup>, 2017

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**Approvals**

Signing below indicates agreement that the protocol is ready for execution of the Installation and Operational Qualification for the Caron 7000 Environmental Chambers Stability Oven located at Giles Chemical QA Laboratory, 102 Commerce Street in Waynesville, NC.

| Project Team Member | Functional Area | Signature              | Date    |
|---------------------|-----------------|------------------------|---------|
| Ashley Williams     | QA Laboratory   | <i>Ashley Williams</i> | 1/16/17 |
| Patrick Owen        | Engineering     | <i>Patrick Owen</i>    | 1/16/17 |
| Matt Haynes         | Operations      | <i>Matt Haynes</i>     | 1-16-17 |
| Deborah Durbin      | Quality         | <i>Deborah Durbin</i>  | 1-16-17 |

A final summary report that consists of results and conclusions based on the data collected after protocol execution will be written and approved. The executed protocol will be attached behind the report.

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**I. PURPOSE:**

The purpose of this protocol is to certify with documented evidence that the Stability Oven is installed and functions as intended. This protocol sets forth the objectives, methodology, documentation, and test activities needed to complete the Installation Qualification (IQ) and Operational Qualification (OQ) for the Caron 7000 Environmental Chambers located at Giles Chemical QA Laboratory, 102 Commerce Street, Waynesville, NC.

**II. BACKGROUND:**

Giles Chemical, a division of Premier Magnesia (Giles), is dedicated to offering high quality Magnesium Sulfate products. To help achieve this goal, stability samples must be stored in an affective sometimes must be efficiently dried for laboratory analysis for quality purposes.

**III. OVERVIEW**

No other departments or systems will be affected by the installation or use of this equipment.

The following tests will be performed in this qualification:

Installation Documentation – the serial number or asset tag number of the Stability Oven will be documented.

Utility Verification – the voltage to the Stability Oven will be documented and verified to be correct.

Control / Operation Verification – the controls will be verified.

**IV. SYSTEM DESCRIPTION:**

A. The system consists of a Caron 7000 Environmental Chambers.

B. Description of Operation

01. The Stability Oven is started by pressing the power button.

02. The Stability Oven heats up to desired temperature.

**V. SCOPE**

The Installation and Operational Qualification protocol is intended to certify with documented evidence that the Stability Oven is installed properly and functions as desired by Giles.

**VI. ROLES AND RESPONSIBILITIES**



1. QA Laboratory

- ❖ Write and issue the protocol
- ❖ Investigate protocol deviation reports
- ❖ Execute the IQ and OQ.
- ❖ Review raw data and originate interim notification to Quality Assurance
- ❖ Write and route the final report

2. Quality Assurance

- ❖ Review and approve the protocol.

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- ❖ Review and approve raw data and notifications.
- ❖ Review, approve, and store the final report.

## VII. TEST PROGRAM

### A. INSTALLATION QUALIFICATION

#### Objective

The objective of the installation verification is to document the proper installation of the Stability Oven

#### Equipment/Materials

Caron 7000 Environmental Chambers Stability Oven

#### Procedure



Perform each item listed below for the Stability Oven.

- Location: Verify that the equipment is situated to allow sufficient room around the equipment for access doors and panels to be opened.
- Equipment: Document the Model and Serial or Asset Tag number of the Stability Oven.
- Utilities
  - Electrical Requirements: Verify the Stability Oven is receiving the specified voltage.

#### Acceptance Criteria

If the voltage is correct, each piece uniquely identified, and sufficient access for all doors and panels is available, the Stability Oven will be considered installed properly.

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## B. OPERATION QUALIFICATION

### Objective

The objective of Controls Verification is to document that the Stability Oven operates as needed by Giles. The controls will be operated to test the ability of the Stability Oven to be operated as needed.

### Equipment/Materials

Caron 7000 Environmental Chambers Stability Oven

### Procedure

Turn the Stability Oven on by pressing the power button.

Verify that the Stability Oven reaches desired temperature using the calibrated independent sensor.

### Acceptance Criteria

If the Stability Oven powers up and reaches the desired temperature then the Stability Oven is considered to be operationally qualified.

## VIII. CALIBRATION

Verify that all instrumentation that requires calibration is calibrated.

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**Stability Oven: INSTALLATION QUALIFICATION****A. Installation Qualification****01. Location**

a. Stability Oven:

| LOCATION   |   |             |      |
|--|---|-------------|------|
| Distance Criterion   | Is the current area sufficient to open the access without obstructions (Yes/No) | Verified By | Date |
| Allow sufficient room around the oven for access doors and panels to be opened |   |             |      |

**02. Equipment Identification**

| EQUIPMENT IDENTIFICATION |                          |             |      |
|--------------------------|--------------------------|-------------|------|
| Equipment                | Serial or Tag Identifier | Verified By | Date |
| Stability Oven           |                          |             |      |
| Comments:                |                          |             |      |

**03. Utilities**



a. Verify that the system is receiving its specified utility requirements.

| ELECTRICAL          |        |             |      |
|---------------------|--------|-------------|------|
| Specified           | Actual | Verified By | Date |
| 115V Stability Oven |        |             |      |
| Comments:           |        |             |      |

Reviewed By: \_\_\_\_\_

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Date: \_\_\_\_\_

|   |   |                         |  |
|---|---|-------------------------|--|
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**Stability Oven: OPERATIONAL QUALIFICATION**

**B. Operation Qualification**



**01. Controls Verification** – to document that the Stability Oven controls work properly

| CONTROLS/INDICATORS VERIFICATION |   |                                     |             |      |
|----------------------------------|---|-------------------------------------|-------------|------|
| Description                      | Function  | Did Item function properly (Yes/No) | Verified By | Date |
| STABILITY OVEN                   |   |                                     |             |      |
| Power Button                     | With line power to the instrument, does pushing the Power Button cause the Stability Oven to heat up? |                                     |             |      |
| Temperature Setting              | With the Stability Oven powered on does it reach the desired temperature?                             |                                     |             |      |

**Reviewed By:** \_\_\_\_\_ **Date:** \_\_\_\_\_

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# ATTACHMENT I - PROTOCOL DEVIATION REPORT LOG



Log each Protocol Deviation Report in the table below. Attach the PDRs to this Attachment.

| PDR #     | DESCRIPTION | DATE INITIATED | DATE RESOLVED |
|-----------|-------------|----------------|---------------|
|           |             |                |               |
|           |             |                |               |
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| Comments: |             |                |               |

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**IX. PROTOCOL DEVIATION REPORT (PDR)**

**General Information**

System Name: \_\_\_\_\_ Protocol Number: \_\_\_\_\_  
 Deviation Report Number: \_\_\_\_\_ Protocol Step & Page No.: \_\_\_\_\_

**Instructions**

InstructionsThe validation specialist assigns a sequential report number for each deviation with a specific protocol.  
 For example, 001, 002, etc. can be easily referenced in a report.

1. Reference the relevant protocol number, step and page number of the noted deviation above.
2. Complete the below listed sections. If necessary, use additional pages and attach any supporting info.
3. Include the original PDR(s) with the protocol as an attachment. Summarize the impact of the deviation in the Validation Report.

=====

Description of Deviation:

Investigation Evaluation and Results:

Corrective Action and Resolution:

=====

Overall Investigation Review:

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Prepared By: \_\_\_\_\_ Date: \_\_\_\_\_

**ATTACHMENT III - SIGNATURE IDENTIFICATION LOG SHEET**

Identify in the table below any personnel involved in the execution of this protocol.

| Name | Affiliation | Signature | Initial | Date |
|------|-------------|-----------|---------|------|
|      |             |           |         |      |
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