

Validation Protocol

Title: Drying Oven IQ/OQ Final Report Number: L14-VAL-100-058

Owner: John Safi Revision: 0

Effective Date: July 22,2014 Page: 1 of 10



Approvals

Signing below indicates agreement that the validation protocol for the Installation and Operational Qualification of the Quincy Labs 20GC Drying Oven located at Giles Chemical QA Laboratory, 102 Commerce Street in Waynesville, NC has been completed and approved.

Project Team Member	Functional Area	Signature	Date
John Safi	QA Laboratory	The Sti	7/22/14
Patrick Owen	Engineering	Perseel	7/22/14
Matt Haynes	Operations	Clubb	1/22/14
Deborah Durbin	Quality	DRushin	7/22/14

This document contains the final summary report that consists of results and conclusions based on the data collected after protocol execution. The executed protocol is attached behind the report.



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I. PURPOSE:

The purpose of this protocol is to certify with documented evidence that the Drying 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 Quincy Labs 20GC Drying Oven 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, product samples 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 Drying Oven will be documented.

Utility Verification – the voltage to the Drying 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 Quincy Labs 20GC Drying Oven.
- B. Description of Operation
 - 01. The Drying Oven is started by pressing the power button.
 - 02. The Drying Oven heats up to desired temperature.

V. SCOPE

The Installation and Operational Qualification protocol is intended to certify with documented evidence that the Drying 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 Drying Oven

Equipment/Materials

Quincy Labs 20GC Drying Oven

Procedure

Perform each item listed below for the Drying 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 Drying Oven.
- Utilities
 - o Electrical Requirements: Verify the Drying 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 Drying Oven will be considered installed properly.



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B. OPERATION QUALIFICATION

Objective

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

Equipment/Materials

Quincy Labs 20GC Drying Oven

Procedure

Turn the Drying Oven on by pressing the power button.

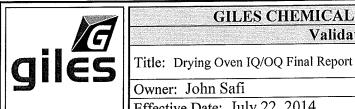
Verify that the Drying Oven reaches desired temperature.

Acceptance Criteria

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

VIII. CALIBRATION

Verify that all instrumentation that requires calibration is calibrated.



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Drying Oven: INSTALLATION QUALIFICATION

A. Installation Qualification

01. Location

a. Drying 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	YES	JS	07/18/2014	

02. Equipment Identification

EQUIPMENT IDENTIFICATION				
Equipment	Serial or Tag Identifier	Verified By	Date	
Drying Oven	G2-6409	JS	07/18/2014	
Comments:		N/A		

03. Utilities

Verify that the system is receiving its specified utility requirements.

ELECTRICAL					
Specified	Actual	Verified By	Date		
110 – 120 V Drying Oven	116.0	JS	07/18/2014		
Comments:					

Reviewed By:

Date: Controlled Document



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Drying Oven: OPERATIONAL QUALIFICATION

B. Operation Qualification

01. Controls Verification - to document that the Drying Oven controls work properly

CONTROLS/INDICATORS VERIFICATION						
Description	Function	Did Item function properly (Yes/No)	Verified By	Date		
	DRYING OVEN					
Power Button	With line power to the instrument, does pushing the Power Button cause the Drying Oven to heat up?	YES	JS	07/18/2014		
Temperature Setting	With the Drying Oven powered on does it reach the desired temperature?	YES	JS	07/18/2014		

Reviewed By:

Jose Jades

Date:

07/18/14



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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
	į.		
Comments:			



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X. PROTOCOL DEVIATION REPORT (PDR)

General Information

System Name:	Protocol Number:
Deviation Report Number:	Protocol Step & Page No.:
	Instructions
InstructionsThe validation F	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 proto	ocol number, step and page number of the noted deviation above.
2. Complete the below listed se	ections. If necessary, use additional pages and attach any supporting info.
Report.	with the protocol as an attachment. Summarize the impact of the deviation in the Validation
escription of Deviation:	
vestigation Evaluation and Results:	
orrective Action and Resolution:	
Micetive Action and Resolution.	
result Investigation Devices	=======================================
verall Investigation Review:	
renared By:	Date:
-11.	Controlled Document
	CONTROLL DOCUMENT



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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
The Sk	Quality Lab	Jun St	75	2/22/14
	,			