Approvals

Signing below indicates agreement that the validation protocol for the Installation and Operational Qualification of the Analytical Balance located at 102 Commerce Street in Waynesville, NC has been completed and approved.

Project Team Member	Functional Area	Signature	Date
John Safi	QA Laboratory	John Safi	7/22/14
Patrick Owen	Engineering		7/22/14
Matt Haynes	Operations		7/22/14
Deborah Durbin	Quality		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 Analytical Balance 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 Mettler Toledo Model XS 105 Duel Range Analytical Balance 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, accurate measurements of mass are required by using an analytical balance.

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 Analytical Balance will be documented.

Utility Verification – the voltage to the Analytical Balance 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 Mettler Toledo Model XS 105 Duel Range Analytical Balance.

B. Description of Operation

01. The Analytical balance is started by pressing the power button.

02. The Analytical Balance is tared by pressing the tare button

03. Material is then weighed.

V. SCOPE

The Installation and Operational Qualification protocol is intended to certify with documented evidence that the Analytical Balance 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.
   - ❖ 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 Analytical Balance.

Equipment/Materials

Mettler Toledo Model XS 105 Duel Range Analytical Balance

Procedure

Perform each item listed below for the Analytical Balance.

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

Acceptance Criteria

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

B. OPERATION QUALIFICATION

Objective

The objective of Controls Verification is to document that the Analytical Balance operates as needed by Giles. The controls will be operated to test the ability of the Analytical Balance to be started and tared as needed.

Equipment/Materials

Analytical Balance

Procedure

Turn the Analytical Balance on by pressing the power button.

Place a weight on the Analytical Balance and press the tare button. Verify that the Analytical Balance tares properly.

Acceptance Criteria

If the Analytical Balance powers up and tares properly then the Analytical Balance is considered to be operationally qualified.

VIII. CALIBRATION

Verify that all instrumentation that requires calibration is calibrated.

- Mettler Toledo Model # XS 105 Duel Range (SN B139292316)

Analytical Balance: INSTALLATION QUALIFICATION

A. Installation Qualification

01. Location

a. Analytical Balance:

LOCATION			
Distance Criterion	**Is the current area sufficient to open the access without obstructions (Yes/No)**	**Verified By**	**Date**
Allow sufficient room around the instrument for access doors and panels to be opened	**YES**	**JS**	**7/22/2014**
The Analytical Balance should be level.	**YES**	**JS**	**7/22/2014**

02. Equipment Identification

EQUIPMENT IDENTIFICATION			
Equipment	**Serial or Tag Identifier**	**Verified By**	**Date**
Analytical Balance	**B139292316**	**JS**	**7/22/2014**
Comments:	**N/A**		

03. Utilities

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

ELECTRICAL			
Specified	**Actual**	**Verified By**	**Date**
110 – 120 V Analytical Balance	**110**	**JS**	**7/22/2014**
Comments:	**N/A**		

Reviewed By: _____ **Date:** _____

Analytical Balance: OPERATIONAL QUALIFICATION

B. Operation Qualification

01. Controls Verification – to document that the Analytical Balance controls work properly

CONTROLS/INDICATORS VERIFICATION				
Description	**Function**	**Did Item function properly (Yes/No)**	**Verified By**	**Date**
ANALYTICAL BALANCE				
Power Button	With line power to the instrument, does pushing the Power Button cause the Analytical Balance to start?	**YES**	**JS**	**7/22/2014**
Tare Button	With a weight on the Analytical Balance, does pushing the Tare Button cause the balance to go to zero?	**YES**	**JS**	**7/22/2014**

Reviewed By: _____ **Date:** _____

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
Comments:			

X. 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:

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
John Safi	Quality Lab	John Safi	JS	7/22/14