Approvals

Signing below indicates agreement that the protocol is ready for execution of the Installation and Operational Qualification for the VWR Symphony SB20 pH Meter located at 102 Commerce Street in Waynesville, NC.

Project Team Member	Functional Area	Signature	Date
Hunter Douglas	QA Laboratory		7/1/2015
Patrick Owen	Engineering		7/1/15
Matt Haynes	Operations		7/1/15
Deborah Durbin	Quality		7/1/15

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 VWR Symphony SB20 pH meter 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) and Performance Qualification (PQ) for the pH meter 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. According to the USP monograph for Magnesium Sulfate the pH of the final crystalline product must be 5.0-9.2 therefore an accurate measure of pH is necessary for compliance.

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 pH Meter will be documented.

Utility Verification – the voltage to the pH Meter will be documented and verified to be correct.

Control / Operation Verification – the controls will be verified.

Performance Verification – The unit will be calibrated and its accuracy checked against known pH standards.

V. SYSTEM DESCRIPTION:

A. The system consists of a VWR Symphony SB20 pH Meter.

B. Description of Operation

01. The Meter is started by pressing the power button.

02. The unit is calibrated by pressing the CAL button.

03. A series of standards which bracket your desired pH range are read and saved into the system which automatically produces a calibration curve.

04. Once the curve is saved the pH can accurately be determined.

V. SCOPE

The Installation, Operational, and Performance Qualification protocol is intended to certify with documented evidence that the pH Meter is installed properly, functions as desired by Giles, and performs accurately.

I. ROLES AND RESPONSIBILITIES

1. QA Laboratory

- ❖ Write and issue the protocol
- ❖ Investigate protocol deviation reports

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- ❖ Execute the IQ, OQ, and PQ.
- ❖ 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 pH meter.

Equipment/Materials

VWR Symphony SB20 pH Meter

Voltmeter

Procedure

Perform each item listed below for the pH Meter.

- Location: Verify that the equipment is situated to allow sufficient room around the instrument for access to buttons and the display can be easily read.
- Equipment: Document the Model and Serial or Asset Tag number of the pH Meter.
- Utilities: Using a voltmeter, verify that the pH Meter is receiving the proper voltage.

Acceptance Criteria

If the voltage is correct, each piece uniquely identified, and there is sufficient room for access and operation, the pH Meter will be considered installed properly.

B. OPERATION QUALIFICATION

Objective

The objective of the operational qualification is to document that the pH Meter operates as needed by Giles. The controls will be operated to test the ability of the pH meter to be started and calibrated as needed.

Equipment/Materials

pH Meter

Procedure

Turn the pH Meter on by pressing the power button.

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Press the CAL button to verify that the meter enters the calibration mode.

Acceptance Criteria

If the pH Meter powers up and enters the calibration mode properly then the pH Meter is considered to be operationally qualified.

C. PERFORMANCE QUALIFICATION

Objective

The objective of the performance qualification is to verify with documented evidence that the pH Meter performs accurately and reliably. The meter will be calibrated with a series of standards and will then check the standards in the 'Measure' mode.

Equipment/Materials

pH Meter

pH Buffers (4,7, and 10)

Lint-free wipes

Di Water

Procedure

With the meter in 'CAL' mode, insert the probe into the first buffer solution. Wait until the reading is steady and the display reads 'ready'. If the reading is not accurate, press the SCROLL button until the correct value is obtained using the OK button to move the adjustment pane to the next digit.

Repeat the process above with the remaining two buffers, remembering to rinse and dry the probe in-between each buffer.

Once the calibration is completed the instrument will display a slope and enter the 'measure' mode.

Repeat the buffer sequence in 'measure' mode.

Acceptance Criteria

If the pH meter accepts the buffer calibration and produces a slope between 92-102% and the buffer check produces values that are no more than ± 0.02 then the pH Meter is considered performance qualified.

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pH Meter: INSTALLATION QUALIFICATION

A. Installation Qualification

01. Location -

a. pH Meter:

LOCATION			
Distance Criterion	**Is the current area sufficient to access without obstructions (Yes/No)**	**Verified By**	**Date**
Allow sufficient room around the instrument for access and easy visual of display.	Yes	HD	7/1/2015

02. Equipment Identification -

EQUIPMENT IDENTIFICATION			
Equipment	**Serial or Tag Identifier**	**Verified By**	**Date**
pH Meter	00005645	HD	7/1/2015
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	115.1 V	HD	7/1/2015
Comments:	N/A		

Reviewed By: John Sch **Date:** 7/1/15

Analytical Balance: OPERATIONAL QUALIFICATION

B. Operation Qualification

01. Controls Verification – to document that the pH Meter controls work properly

CONTROLS/INDICATORS VERIFICATION				
Description	**Function**	**Did Item function properly (Yes/No)**	**Verified By**	**Date**
pH METER				
POWER Button	With line power to the instrument, does pushing the Power Button cause the pH Meter to start?	Yes	HD	7/1/15
CAL Button	With a weight on the pH Meter, does pushing the CAL Button cause the meter to enter the calibration mode?	Yes	HD	7/1/15

Reviewed By: John Sal **Date:** 7/1/15

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C. **Performance Qualification**

01. Calibration –

PERFORMANCE				
Operation	**Criteria**	**Value**	**Verified By**	**Date**
Calibrate the pH meter with 4, 7, and 10 buffers to obtain a slope	**92-102%**	99.3%	HD	7/1/2015
Comments:	N/A			

02. Buffer Check –

MEASUREMENT PERFORMANCE						
Operation	**pH 4.00 Buffer**	**pH 7.00 Buffer**	**pH 10.00 Buffer**	**All Buffers within ± 0.02 of stated value**	**Verified By**	**Date**
Buffer Check	3.98	6.99	10.01	Yes	HD	7/1/2015
Comments	N/A					

Reviewed By: John Sch **Date:** 7/1/15

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:			

III. 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.

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Description of Deviation:

Investigation Evaluation and Results:

Corrective Action and Resolution:

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Overall Investigation Review:

Prepared By: _____ Date: _____

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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
Hunter Douglas	QA Laboratory		HD	7/1/2015
John Sofi	QA Laboratory		JS	7/1/15