Approvals

Signing below indicates agreement that the protocol is ready for execution of the Installation, Operational, and Performance Qualification for the manual lines located at 396 Smathers Street in Waynesville, NC.

Project Team Member	Functional Area	Signature	Date
Patrick Owen	Engineering		6/17/13
Robert Willis	Maintenance		6/17/13
Monte Plott	Production		6/18/13
Matt Haynes	Operations		6/19/13
Deborah Durbin	Quality		6/17/13

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 Manual Lines, function as intended throughout their anticipated operating ranges. This protocol sets forth the objectives, methodology, documentation, and test activities needed to complete the Installation Qualification (IQ), Operational Qualification (OQ) and Process Qualification (PQ) for the Manual Lines located at Giles Chemical Repackaging Unit, 396 Smathers Street, Waynesville, NC.

II. BACKGROUND:

The Manual Lines consist of 4 small packaging machines that are utilized to pack low volume and/or alternate shaped packages of Epsom Salt. They are used also to package products normally packaged on other machines, but the extra volume is needed to fill orders.

The products that are impacted by this study are all Epsom Salt products manufactured by Giles Chemical.

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:

Controls Verification – Verify the fill switch works

Lot code and expiration date verification: Verification of proper imprinting of the lot code.

Sealed pouch: Verification that the sealer securely seals the pouch.

Fill Weights: Verify that each Manual Line is capable of producing a finished product that contains a weight of Epsom Salt with a minmum of the label stated weight.

IV. SYSTEM DESCRIPTION:

A. Each Manual Line consists of: an AMS Auger Filler, and Emplex Sealer, and a Kortho Date Coder. There are 4 manual lines in place and at any time 2 of them are usually in operation.

B. Description of Operation

01. The empty pouches are manually fed into the Kortho date coding machine one by one. The date coder machine stamps the date code on the pouch.

02. The pouch is then handed to the Filler Operator. The Filler Operator opens the pouch, places it under the Auger Filler and presses the fill switch. The pouch is then filled. The Auger filler has adjustments for the number of rotations that control the amount filled.

03. The pouch is placed of a small conveyor that is part of a Sealer. The Sealer then heat selas the pouch.

04. Finally the pouch is conveyed out of the Sealer and onto a packing table. The pouches are then manually packed into case packaging.

V. SCOPE

The Installation Operational Performance Qualification protocol is intended to certify with documented evidence that the Manual Lines are installed, operate, and function as intended.

VI. ROLES AND RESPONSIBILITIES

1. Engineering
   - ❖ Write and issue the protocol
   - ❖ Investigate protocol deviation reports
   - ❖ Execute the OQ and manage the data collection for the 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.
3. Maintenance
   - ❖ Provide Equipment Manuals needed to execute operational qualification.
   - ❖ Review and approve the protocol.
   - ❖ Execute the IQ.
   - ❖ Review and approve raw data and notifications.
   - ❖ Review and approve the final report
4. Production
   - ❖ Execute the PQ.
   - ❖ Review and approve the final report.

VII. TEST PROGRAM

A. INSTALLATION QUALIFICATION

Objective

The objective of the installation verification is to document each piece of Manual Line equipment.

Equipment/Materials

Manual Lines #1 - #4

Ideal Digital Multimeter Model #61-340 (SN 100100221)

Procedure

Perform each listed below for Manual Lines #1 - #4

- Location: Verify that the equipment is situated to allow sufficient room around the machine for access doors and panels to be opened.
- Equipment: Document the Model and Serial or Asset Tag number of each piece of each manual line.
- Utilities
    - Electrical Requirements: Verify that instrument is receiving its specified Voltage.

Acceptance Criteria

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

B. OPERATION QUALIFICATION

Objective

The objective of Controls Verification is to document that the Manual Lines operate as needed by Giles. The controls will be operated to test the ability the Manual Lines to provide adequate control for filling..

Equipment/Materials

Manual Lines #1 - #4

Procedure

Test the filling of each Manual Line by operating the fill switch.

Acceptance Criteria

Verification that the Auger Filler Dispenses when the fill switch is operated.

C. PERFORMANCE QUALIFICATION

Objective

The objective of performance testing is to document that Manual Lines #1-#4 perform the function required by Giles Chemical. The final product will be tested to verify:

- That each Manual Line firmly seals pouch.
- That the date code is printed properly and accurately.
- That the fill weights are within the accepted range (3.0+ pounds for 3 pound pouches).

Equipment/Materials

Manual Lines #1 - #4

Empty Pouch(es) (for tare)

Scale

Procedure

Run each Manual Line for 2 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 50 pouches.

Examine the finished product and check for:

- The Manual Line firmly seals the pouch.
- That the date code is imprinted properly and accurately.
- That the fill weights are within the accepted range (>stated on pouch).

Acceptance Criteria

Manual Lines #1 - #4 seal 100% of the pouches tested.

Manual Lines #1 - #4 imprint the date code correctly in 100% of the pouches tested.

That the fill weights are within the accepted range of greater than stated on pouch.

VIII. CALIBRATION

Verify that all instrumentation that requires calibration is calibrated.

- Scale
- Ideal Digital Multimeter Model #61-340 (SN 100100221)

Manual Lines: INSTALLATION QUALIFICATION

A. Installation Qualification

01. Location

a. Verify that Manual Line #1 is located properly:

LOCATION			
Distance Criterion	**Is the current area sufficient to open the access without obstructions (Yes/No)**	**Verified By**	**Date**
Allow sufficient room around the machine for access doors and panels to be opened			
The machine must be located in an area that is adequately ventilated			

b. Verify that Manual Line #2 is located properly:

LOCATION			
Distance Criterion	**Is the current area sufficient to open the access without obstructions (Yes/No)**	**Verified By**	**Date**
Allow sufficient room around the machine for access doors and panels to be opened			
The machine must be located in an area that is adequately ventilated			

c. Verify that Manual Line #3 is located properly:

LOCATION			
Distance Criterion	**Is the current area sufficient to open the access without obstructions (Yes/No)**	**Verified By**	**Date**
Allow sufficient room around the machine for access doors and panels to be opened			
The machine must be located in an area that is adequately ventilated			

d. Verify that Manual Line #4 is located properly:

LOCATION			
Distance Criterion	**Is the current area sufficient to open the access without obstructions (Yes/No)**	**Verified By**	**Date**
Allow sufficient room around the machine for access doors and panels to be opened			
The machine must be located in an area that is adequately ventilated			

Reviewed By: _____ **Date:** _____

02. Equipment Identification

Equipment Identification			
Equipment	**Serial or Tag Identifier**	**Verified By**	**Date**
Manual Line #1			
Date Coder (Kortho)			
Auger Filler (AMS)			
Sealer (Emplex)			
Manual Line #2			
Date Coder (Kortho)			
Auger Filler (AMS)			
Sealer (Emplex)			
Manual Line #3			
Date Coder (Kortho)			
Auger Filler (AMS)			
Sealer (Emplex)			
Manual Line #4			
Date Coder (Kortho)			
Auger Filler (AMS)			
Sealer (Emplex)			
Comments:			

Reviewed By: _____ **Date:** _____

03. Utilities

a. Verify that unit is receiving its specified utility requirements.

Electrical			
Specified	**Actual**	**Verified By**	**Date**
210 – 240 V Manual Line #1			
210 – 240 V Manual Line #2			
210 – 240 V Manual Line #3			
210 – 240 V Manual Line #4			
Comments:			

Reviewed By: _____ **Date:** _____

Manual Lines: OPERATIONAL QUALIFICATION

B. Operation Qualification

01. Controls Verification – to document that the Manual Lines dispense and seal

Controls/Indicators Verification				
Description	**Function**	**Did Item function properly (Yes/No)**	**Verified By**	**Date**
Manual Line #1				
Fill Switch	With line power to the machine, does tripping the Fill Switch cause the Machine to Dispense?			
Sealer Switch	When the sealer switch is in the On position does the sealer heat up and conveyor work?			
Manual Line #2				
Fill Switch	With line power to the machine, does tripping the Fill Switch cause the Machine to Dispense?			
Sealer Switch	When the sealer switch is in the On position does the sealer heat up and conveyor work?			
Manual Line #3				
Fill Switch	With line power to the machine, does tripping the Fill Switch cause the Machine to Dispense?			
Sealer Switch	When the sealer switch is in the On position does the sealer heat up and conveyor work?			
Manual Line #4				
Fill Switch	With line power to the machine, does tripping the Fill Switch cause the Machine to Dispense?			
Sealer Switch	When the sealer switch is in the On position does the sealer heat up and conveyor work?			
Comments:				

Reviewed By: _____ **Date:** _____

Manual Lines: PERFORMANCE QUALIFICATION

A. Firmly Sealed: Verify that Manual Line firmly seals the pouch.

Run Manual Line for 2 hours while randomly sampling 25 pouches per hour for testing, a total sample size of 50 pouches.

Manual Line #:	**1 2 3 4 (Circle one)**	**Trial**		**of 2**
Sample #	**Is the pouch sealed? (Yes/No)**	**Is the pouch scorched? (Yes/No)**	**Does the seal leak? (Yes/No)**	**Verified By**	**Date**
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					
Comments:					

Reviewed By: _____ **Date:** _____

MANUAL LINES: PERFORMANCE QUALIFICATION (Continued)

B. Date Code Imprinting: Verify that the date code is imprinted properly and accurately.
Run each Manual Line for 2 hours while randomly sampling 25 pouches per hour for testing, a total sample size of 50 pouches.

Manual Line #: 1 2 3 4 (Circle one)			Trial		of 2
Sample #	Is the Date Code visible? (Yes/No)	Is the Date Code correct? (Yes/No)	Verified By	Date	
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					
Comments:					

Reviewed By: _____ **Date:** _____

MANUAL LINES: PERFORMANCE QUALIFICATION (Continued)

C. Fill Weights: Verify that the fill weights are within the accepted range >= Pouch Stated Weight
Run each Line for 2 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 50 pouches.

Manual Line #: 1 2 3 4 (Circle one)				Trial		of 2
Sample #	**Actual Weight**	**Pouch Stated Weight**	**Acceptable (Yes/No)**	**Verified By**	**Date**	
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
Comments:						

Reviewed By: _____ **Date:** _____

MANUAL LINES: CALIBRATION VERIFICATION

Equipment	Serial #	Calibration Date	Calibration Due Date	Verified By	Date
Scale					
Multimeter					

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

1. The 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.
2. Reference the relevant protocol number, step and page number of the noted deviation above.
3. Complete the below listed sections. If necessary, use additional pages and attach any supporting info.
4. 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