Approvals

Signing below indicates agreement that the execution of the Installation, Operational, and Performance Qualification Protocol for Carton Machine #1, Evergreen Q-11 located at 396 Smathers Street at the Repackaging facility is complete and the process is validated.

Project Team Member	Functional Area	Signature	Date
Patrick Owen	Engineering		1/15/14
Sammy Henson	Maintenance		1/15/14
Monte Plott	Production		1/15/14
Matt Haynes	Operations		1/15/14
Deborah Durbin	Quality		1/15/14

A copy of the executed protocol will be attached behind this report.

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I. PURPOSE:

The purpose of the protocol is to certify with documented evidence that the Epsom Salt Carton Machine #1 (Evergreen Q-11 Serial #7032), functions as intended throughout its anticipated operating ranges. This final report provides documented evidence that the objectives, methodology, documentation, and test activities needed to complete the Installation Qualification (IQ), Operational Qualification (OQ) and Process Qualification (PQ) for the Epsom Salt Carton Machine #1 located at Giles Chemical Repackaging Unit, 396 Smathers Street, Waynesville, NC were all executed and all acceptance criteria were met.

II. SUMMARY

This Epsom Salt Carton Machine Model Q-11 (serial #7032) was manufactured by Evergreen, Inc and purchased used from Aaron Industries in Clinton, SC. Aaron Industries had the machine modified for use with Epsom Salt and it was installed at Giles in September of 2013. The machine is used to fill 1 and 2 pound cartons.

The products that are impacted by this study were all Epsom Salt products manufactured by Giles Chemical. No other departments or systems were be affected by the installation or use of this equipment.

The following tests were performed in this qualification:

Controls/Indicators Verification – to verify and document that Epsom Salt Carton Machine #1 oven, start/stop, and infeed controls operate as described by the manufacture.

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

Sealed box: Verification that the Epsom Salt Carton Machine securely seals the carton at both ends.

Fill Weights: Verification that the Epsom Salt Carton Machine is capable of producing a finished product that contains a weight of Epsom Salt with a minmum of the label stated weight.

All Installation, Operational, and Performance acceptance criteria were met as displayed in the tables in the Appendices.

III. CONCLUSION

The results of the completed Installation Operational Performance Qualification protocol show that all acceptance criteria were met for all samples. All testing results provide documented evidence that Epsom Salt Carton Machine #1 (Evergreen Q-11 Serial #7032) is installed, operating, and performing as expected. Epsom Salt Carton Machine #1 (Evergreen Q-11 Serial #7032) is considered validated.

IV. RECOMMENDATIONS

1. It is recommended that Epsom Salt Carton Machine #1 (Evergreen Q-11 Serial #7032), located at Giles Chemical Repackaging, 396 Smathers Street, Waynesville, NC 28786 be considered validated based on meeting the acceptance criteria of the IQ/OQ/PQ protocol.

V. REFERENCE:

Operating Manual for Evergreen Q-11 Carton Machine

E13-VAL-RIQ-101, Carton Machine 1 IQ/OQ/PQ Protocol, rev1,1/10/2014

Appendix I: INSTALLATION QUALIFICATION

A. Installation Qualification

01. Location

a. Verify that Epson Salt Filling Machine is positioned properly

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

02. Level

a. It is important to make sure that the Epsom Salt Filling Machine is level.

Is the unit level? (Yes/No)	Acceptable (Yes/No)
YES	YES

03. Utilities

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

Specified	Actual
230 V for Machine Minimum	230
115V for Controls	120
60 Hz	60
A valve should be located at the inlet to the machine to control flow	Yes

Appendix II: OPERATIONAL QUALIFICATION

1. **Controls/Indicators Verification** – to document that the Epsom Salt Filling Machine operates as described.

Description	Function	Did Item function properly (Yes/No)
Controls On/Off	With line power to the machine turned on, the controls switch powers up the control panel	YES
Vacuum	The vacuum switch applies vacuum to the carton picker manifold to start cartons feeding into the machine. With the vacuum switch off, the machine may be cycled for service checks and warm-up without running cartons.	YES
Jog/Run	In jog position, and filler auto switch on, the filler will index under control of the fill timer. To "jog" the former, the index start switch must be pressed. In run position, the vacuum pump motor and the start button light will be turned on.	YES
Carton Feed	When line 1 feed switch is engaged, the carton blanks from line 1 will feed into the machine. When line 2 feed switch is engaged, carton blanks from line 2 will feed. These switches operate independently.	YES
Oven Ignition	When the oven ignition button is pressed, the ovens ignites and begins heating.	YES

Appendix III: PERFORMANCE QUALIFICATION

A. Firmly Sealed: Verify That the Epsom Salt Filling Machine firmly seals the carton on both ends. Run the Epsom Salt Filling Machine for 4 hours while randomly sampling 25 cartons per hour for testing, for a total sample size of 100 cartons.

Table I

Sample #	Is the top sealed? (Yes/No)	Is the top scorched? (Yes/No)	Is the bottom sealed? (Yes/No)	Is the bottom scorched? (Yes/No)
1	YES	NO	YES	NO
2	YES	NO	YES	NO
3	YES	NO	YES	NO
4	YES	NO	YES	NO
5	YES	NO	YES	NO
6	YES	NO	YES	NO
7	YES	NO	YES	NO
8	YES	NO	YES	NO
9	YES	NO	YES	NO
10	YES	NO	YES	NO
11	YES	NO	YES	NO
12	YES	NO	YES	NO
13	YES	NO	YES	NO
14	YES	NO	YES	NO
15	YES	NO	YES	NO
16	YES	NO	YES	NO
17	YES	NO	YES	NO
18	YES	NO	YES	NO
19	YES	NO	YES	NO
20	YES	NO	YES	NO
21	YES	NO	YES	NO
22	YES	NO	YES	NO
23	YES	NO	YES	NO
24	YES	NO	YES	NO
25	YES	NO	YES	NO

APPENDIX III TABLE I CONTINUED

Sample #	Is the top sealed? (Yes/No)	Is the top scorched? (Yes/No)	Is the bottom sealed? (Yes/No)	Is the bottom scorched? (Yes/No)
26	YES	NO	YES	NO
27	YES	NO	YES	NO
28	YES	NO	YES	NO
29	YES	NO	YES	NO
30	YES	NO	YES	NO
31	YES	NO	YES	NO
32	YES	NO	YES	NO
33	YES	NO	YES	NO
34	YES	NO	YES	NO
35	YES	NO	YES	NO
36	YES	NO	YES	NO
37	YES	NO	YES	NO
38	YES	NO	YES	NO
39	YES	NO	YES	NO
40	YES	NO	YES	NO
41	YES	NO	YES	NO
42	YES	NO	YES	NO
43	YES	NO	YES	NO
44	YES	NO	YES	NO
45	YES	NO	YES	NO
46	YES	NO	YES	NO
47	YES	NO	YES	NO
48	YES	NO	YES	NO
49	YES	NO	YES	NO
50	YES	NO	YES	NO

APPENDIX III TABLE I CONTINUED

Sample #	Is the top sealed? (Yes/No)	Is the top scorched? (Yes/No)	Is the bottom sealed? (Yes/No)	Is the bottom scorched? (Yes/No)
51	YES	NO	YES	NO
52	YES	NO	YES	NO
53	YES	NO	YES	NO
54	YES	NO	YES	NO
55	YES	NO	YES	NO
56	YES	NO	YES	NO
57	YES	NO	YES	NO
58	YES	NO	YES	NO
59	YES	NO	YES	NO
60	YES	NO	YES	NO
61	YES	NO	YES	NO
62	YES	NO	YES	NO
63	YES	NO	YES	NO
64	YES	NO	YES	NO
65	YES	NO	YES	NO
66	YES	NO	YES	NO
67	YES	NO	YES	NO
68	YES	NO	YES	NO
69	YES	NO	YES	NO
70	YES	NO	YES	NO
71	YES	NO	YES	NO
72	YES	NO	YES	NO
73	YES	NO	YES	NO
74	YES	NO	YES	NO
75	YES	NO	YES	NO

APPENDIX III TABLE I CONTINUED

Sample #	Is the top sealed? (Yes/No)	Is the top scorched? (Yes/No)	Is the bottom sealed? (Yes/No)	Is the bottom scorched? (Yes/No)
76	YES	NO	YES	NO
77	YES	NO	YES	NO
78	YES	NO	YES	NO
79	YES	NO	YES	NO
80	YES	NO	YES	NO
81	YES	NO	YES	NO
82	YES	NO	YES	NO
83	YES	NO	YES	NO
84	YES	NO	YES	NO
85	YES	NO	YES	NO
86	YES	NO	YES	NO
87	YES	NO	YES	NO
88	YES	NO	YES	NO
89	YES	NO	YES	NO
90	YES	NO	YES	NO
91	YES	NO	YES	NO
92	YES	NO	YES	NO
93	YES	NO	YES	NO
94	YES	NO	YES	NO
95	YES	NO	YES	NO
96	YES	NO	YES	NO
97	YES	NO	YES	NO
98	YES	NO	YES	NO
99	YES	NO	YES	NO
100	YES	NO	YES	NO

PERFORMANCE QUALIFICATION (Continued)

B. Lot Code and Expiration Date Imprinting: Verify that the lot code and expiration date numbers are imprinted properly and accurately.

Run the Epsom Salt Filling Machine for 4 hours while randomly sampling 25 cartons per hour for testing, for a total sample size of 100 cartons.

Table II-

Sample #	Is the Lot Code and Expiration Date visible? (Yes/No)	Is the Lot Code and Expiration Date correct? (Yes/No)
1	Yes	Yes
2	Yes	Yes
3	Yes	Yes
4	Yes	Yes
5	Yes	Yes
6	Yes	Yes
7	Yes	Yes
8	Yes	Yes
9	Yes	Yes
10	Yes	Yes
11	Yes	Yes
12	Yes	Yes
13	Yes	Yes
14	Yes	Yes
15	Yes	Yes
16	Yes	Yes
17	Yes	Yes
18	Yes	Yes
19	Yes	Yes
20	Yes	Yes
21	Yes	Yes
22	Yes	Yes
23	Yes	Yes
24	Yes	Yes
25	Yes	Yes

APPENDIX III TABLE II CONTINUED –

Sample #	Is the Lot Code and Expiration Date visible? (Yes/No)	Is the Lot Code and Expiration Date correct? (Yes/No)
26	Yes	Yes
27	Yes	Yes
28	Yes	Yes
29	Yes	Yes
30	Yes	Yes
31	Yes	Yes
32	Yes	Yes
33	Yes	Yes
34	Yes	Yes
35	Yes	Yes
36	Yes	Yes
37	Yes	Yes
38	Yes	Yes
39	Yes	Yes
40	Yes	Yes
41	Yes	Yes
42	Yes	Yes
43	Yes	Yes
44	Yes	Yes
45	Yes	Yes
46	Yes	Yes
47	Yes	Yes
48	Yes	Yes
49	Yes	Yes
50	Yes	Yes

APPENDIX III TABLE II CONTINUED –

Sample #	Is the Lot Code and Expiration Date visible? (Yes/No)	Is the Lot Code and Expiration Date correct? (Yes/No)
51	Yes	Yes
52	Yes	Yes
53	Yes	Yes
54	Yes	Yes
55	Yes	Yes
56	Yes	Yes
57	Yes	Yes
58	Yes	Yes
59	Yes	Yes
60	Yes	Yes
61	Yes	Yes
62	Yes	Yes
63	Yes	Yes
64	Yes	Yes
65	Yes	Yes
66	Yes	Yes
67	Yes	Yes
68	Yes	Yes
69	Yes	Yes
70	Yes	Yes
71	Yes	Yes
72	Yes	Yes
73	Yes	Yes
74	Yes	Yes
75	Yes	Yes

APPENDIX III TABLE II CONTINUED –

Sample #	Is the Lot Code and Expiration Date visible? (Yes/No)	Is the Lot Code and Expiration Date correct? (Yes/No)
76	Yes	Yes
77	Yes	Yes
78	Yes	Yes
79	Yes	Yes
80	Yes	Yes
81	Yes	Yes
82	Yes	Yes
83	Yes	Yes
84	Yes	Yes
85	Yes	Yes
86	Yes	Yes
87	Yes	Yes
88	Yes	Yes
89	Yes	Yes
90	Yes	Yes
91	Yes	Yes
92	Yes	Yes
93	Yes	Yes
94	Yes	Yes
95	Yes	Yes
96	Yes	Yes
97	Yes	Yes
98	Yes	Yes
99	Yes	Yes
100	Yes	Yes

PERFORMANCE QUALIFICATION (Continued)

C. Fill Weights: Verify that the fill weights are within the accepted range of 1.00+ pounds.
Run the Epsom Salt Filling Machine for 4 hours while randomly sampling 25 cartons per hour for testing, for a total sample size of 100 cartons.

Table III-

Sample #	Actual Weight	Acceptable (Yes/No)
1	1.00	YES
2	1.02	YES
3	1.01	YES
4	1.02	YES
5	1.01	YES
6	1.01	YES
7	1.01	YES
8	1.01	YES
9	1.01	YES
10	1.01	YES
11	1.00	YES
12	1.00	YES
13	1.01	YES
14	1.01	YES
15	1.00	YES
16	1.00	YES
17	1.00	YES
18	1.01	YES
19	1.01	YES
20	1.01	YES
21	1.01	YES
22	1.01	YES
23	1.01	YES
24	1.01	YES
25	1.01	YES

APPENDIX III TABLE III CONTINUED -

Sample #	Actual Weight	Acceptable (Yes/No)
26	1.00	YES
27	1.00	YES
28	1.00	YES
29	1.00	YES
30	1.00	YES
31	1.00	YES
32	1.01	YES
33	1.01	YES
34	1.01	YES
35	1.00	YES
36	1.02	YES
37	1.01	YES
38	1.02	YES
39	1.02	YES
40	1.01	YES
41	1.02	YES
42	1.02	YES
43	1.02	YES
44	1.02	YES
45	1.02	YES
46	1.02	YES
47	1.02	YES
48	1.02	YES
49	1.01	YES
50	1.01	YES

APPENDIX III TABLE III CONTINUED -

Sample #	Actual Weight	Acceptable (Yes/No)
51	1.02	YES
52	1.02	YES
53	1.02	YES
54	1.02	YES
55	1.03	YES
56	1.02	YES
57	1.02	YES
58	1.02	YES
59	1.03	YES
60	1.03	YES
61	1.02	YES
62	1.02	YES
63	1.03	YES
64	1.03	YES
65	1.02	YES
66	1.02	YES
67	1.02	YES
68	1.02	YES
69	1.02	YES
70	1.02	YES
71	1.01	YES
72	1.02	YES
73	1.02	YES
74	1.02	YES
75	1.02	YES

APPENDIX III TABLE III CONTINUED -

Sample #	Actual Weight	Acceptable (Yes/No)
76	1.02	YES
77	1.02	YES
78	1.02	YES
79	1.02	YES
80	1.02	YES
81	1.03	YES
82	1.02	YES
83	1.02	YES
84	1.03	YES
85	1.03	YES
86	1.02	YES
87	1.02	YES
88	1.02	YES
89	1.02	YES
90	1.02	YES
91	1.02	YES
92	1.02	YES
93	1.03	YES
94	1.03	YES
95	1.02	YES
96	1.03	YES
97	1.02	YES
98	1.02	YES
99	1.02	YES
100	1.02	YES

Approvals

Signing below indicates agreement that the protocol is ready for execution of the Installation, Operational, and Performance Qualification Protocol for Carton Machine #1, Evergreen Q-11 located at 396 Smathers Street at the Repackaging facility.

Project Team Member	Functional Area	Signature	Date
Patrick Owen	Engineering		1/10/14
Sammy Henson	Maintenance		1/10/14
Monte Plott	Production		1/10/14
Matt Haynes	Operations		1/10/14
Deborah Durbin	Quality		1/10/14

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.

TABLE OF CONTENTS		Page #

I. PURPOSE:

The purpose of this protocol is to certify with documented evidence that the Epsom Salt Carton Machine #1 (Evergreen Q-11 Serial #7032), functions as intended throughout its 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 Epsom Salt Carton Machine #1 located at Giles Chemical Repackaging Unit, 396 Smathers Street, Waynesville, NC.

II. BACKGROUND:

This Epsom Salt Carton Machine Model Q-11 (serial #7032) was manufactured by Evergreen Packaging, Inc and obtained used from Aaron Industries in Clinton. SC. Aaron Industries previously had the machine modified for use with Epsom Salt and it was installed at Giles on September 8, 2013. The machine is used to make 1 and 2 pound cartons.

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/Indicators Verification – to document that Epsom Salt Carton Machine #1 oven, start/stop, and infeed controls operate as described by the manufacture.

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

Sealed box: Verification that the Epsom Salt Carton Machine securely seals the carton at both ends.

Fill Weights: Verify that the Epsom Salt Carton Machine 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. The Evergreen Q-11 will open, bottom seal, fill, and top seal gable top polyethylene coated cartons with Epsom Salt. It is a 2 line system, opening filling, and sealing 2 cartons at a time.

B. Description of Operation

01. The carton blanks are pulled from the infeed magazines by vacuum cups. The vacuum cups open the carton and square it. The blanks are slid onto the forming mandrel by a chain. The mandrel supports the cartons while the carton bottoms are heated, formed, and sealed. Gas fired ovens direct heated air to activated the sealing areas of the cartons. Vacuum cups then slide the bottom sealed cartons from the mandrel into conveyor pockets formed by the two conveying chains.

02. The cartons are indexed down the filler carriage at the same rate as they are unloaded from the mandrels. The top breakers on the filler carriage crease the tops on the sealing lip. The cartons are indexed into the fill stations by the conveyor. Each carton is then filled by an auger type filler. The carton tops are heated, folded, sealed and indexed out to the carton conveyor.

03. On the carton conveyor, the carton is check weighed (and rejected if the weight is below label weight) and the Lot/Expiration information is applied by Continuous Inkjet.

04. The cartons are then manually packed into case packaging.

V. SCOPE

The Installation Operational Performance Qualification protocol is intended to certify with documented evidence that the Epsom Salt Carton Machine #1 is installed, operates, and functions as intended throughout its anticipated operating ranges.

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 that Epsom Salt Carton Machine #1 is installed as indicated by Cherry Burrell.

Equipment/Materials

Epsom Salt Carton Machine model Q-11 (SN 7032)

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

Procedure

Perform each listed below for the Epsom Salt Carton Machine

- Location: Verify that the equipment is situated to allow sufficient room around the machine for access doors and panels to be opened.
- Level: Verify instrument is level.
- Utilities
  - Electrical Requirements: Verify that instrument is receiving its specified Voltage.

Acceptance Criteria

Ensure that the installation is in accordance with the manual's specifications.

B. OPERATION QUALIFICATION

Objective

The objective of Controls/Indicators Verification is to document that the Epsom Salt Carton Machine #1 operates as indicated by Cherry Burrell, Inc. The controls will be operated to test the ability of the Epsom Salt Carton Machine #1 to provide adequate control for starting/stopping, carton feed, and oven ignition.

Equipment/Materials

Epsom Salt Carton Machine model Q-11 (SN 7032)

Procedure

Test each operation of the Epsom Salt Carton Machine #1

Acceptance Criteria

Verification that start/stop, carton feed, and oven ignition controls function as indicated by operation manual

C. PERFORMANCE QUALIFICATION

Objective

The objective of performance testing is to document that the Epsom Salt Carton Machine #1 performs the function required by Giles Chemical. The final product will be tested to verify:

- That the Epsom Salt Carton Machine firmly seals the carton on both ends.
- That the lot code and expiration date numbers are printed properly and accurately.
- That the fill weights are within the accepted range (1.0+ pounds for 1 pound cartons and 2.0+ pounds for 2 pound cartons).

Equipment/Materials

Epsom Salt Carton Machine model Q-11 (SN 7032)

Empty Carton Blank (for tare)

Scale

Procedure

Run the Epsom Salt Filling Machine on 1 pound cartons for 4 hours while randomly sampling 25 cartons per hour for testing, for a total sample size of 100 cartons.

Examine the finished product and check for:

- That the Epsom Salt Filling Machine firmly seals the carton on both ends.
- That the lot code and expiration date numbers are imprinted properly and accurately.
- That the fill weights are within the accepted range.

Repeat for 2 pound cartons.

Acceptance Criteria

The Epsom Salt Filling Machine firmly seals the carton on both ends.

The Epsom Salt Filling Machine correctly imprints the lot code and expiration date.

That the fill weights are within the accepted range of 1.00+ pounds for 1 pound cartons and 2.00+ pounds for 2 pound cartons.

VIII. CALIBRATION

Verify that all instrumentation that requires calibration is calibrated.

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

IX. REFERENCE:

Operating Manual for Evergreen Carton Machine, March 1985.

EPSOM SALT FILLING MACHINE: INSTALLATION QUALIFICATION

A. Installation Qualification

01. Location

a. Verify that Epson Salt Filling Machine is positioned 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	Yes	PSV	1/13/14
The machine must be located in an area that is adequately ventilated	Yes	PSV	1/13/14
Comments:			PSV 1/13/14

02. Level

a. It is important to make sure that the Epsom Salt Filling Machine is level.

LEVEL			
Is the unit level? (Yes/No)	**Acceptable (Yes/No)**	**Verified By**	**Date**
Yes	Yes	PSV	1/13/14
Comments:			PSV 1/13/14

03. Utilities

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

UTILIES			
Electrical			
Specified	**Actual**	**Verified By**	**Date**
230 +/- 15 V for Machine	230V	PSV	1/13/14
115 +/- 10 V for Controls	120V	PSV	1/13/14
60 Hz	60Hz	PSV	1/13/14
Water			
The machine requires a water connection for cooling			
A valve should be located at the inlet to the machine to control flow	Yes	PSV	1/13/14
Comments:			PSV 1/13/14

Reviewed By: _____ **Date:** 1-13-14

EPSOM SALT FILLING MACHINE: OPERATIONAL QUALIFICATION

B. Operation Qualification

01. Controls/Indicators Verification – to document that the Epsom Salt Filling Machine operates as described.

Controls/Indicators Verification				
Description	**Function**	**Did Item function properly (Yes/No)**	**Verified By**	**Date**
Former				
Controls On/Off	With line power to the machine turned on, the controls switch powers up the control panel	Yes	PSw	1/13/14
Vacuum	The vacuum switch applies vacuum to the carton picker manifold to start cartons feeding into the machine. With the vacuum switch off, the machine may be cycled for service checks and warm-up without running cartons.	Yes	PSw	1/13/14
Jog/Run	In jog position, and filler auto switch on, the filler will index under control of the fill timer. To "jog" the former, the index start switch must be pressed. In run position, the vacuum pump motor and the start button light will be turned on.	Yes	PSw	1/13/14
Carton Feed	When line 1 feed switch is engaged, the carton blanks from line 1 will feed into the machine. When line 2 feed switch is engaged, carton blanks from line 2 will feed. These switches operate independently.	Yes	PSw	1/13/14
Oven Ignition	When the oven ignition button is pressed, the ovens ignites and begins heating.	Yes	PSw	1/13/14
Comments:				

PSw
1/13/14

Reviewed By: _____ **Date:** 1-13-14

EPSOM SALT FILLING MACHINE: PERFORMANCE QUALIFICATION

C. Firmly Sealed: Verify That the Epsom Salt Filling Machine firmly seals the carton on both ends. Run the Epsom Salt Filling Machine for 4 hours while randomly sampling 25 cartons per hour for testing, for a total sample size of 100 cartons.

Firmly Sealed						Trial 1 of 4	
Sample #	Is the top sealed? (Yes/No)	Is the top scorched? (Yes/No)	Is the bottom sealed? (Yes/No)	Is the bottom scorched? (Yes/No)	Verified By	Date
1	Y	N	Y	N	Patrick Owen	1/13/14
2	Y	N	Y	N		
3	Y	N	Y	N		
4	Y	N	Y	N		
5	Y	N	Y	N		
6	Y	N	Y	N		
7	Y	N	Y	N		
8	Y	N	Y	N		
9	Y	N	Y	N		
10	Y	N	Y	N		
11	Y	N	Y	N		
12	Y	N	Y	N		
13	Y	N	Y	N		
14	Y	N	Y	N		
15	Y	N	Y	N		
16	Y	N	Y	N		
17	Y	N	Y	N		
18	Y	N	Y	N		
19	Y	N	Y	N		
20	Y	N	Y	N		
21	Y	N	Y	N		
22	Y	N	Y	N		
23	Y	N	Y	N		
24	Y	N	Y	N		
25	Y	N	Y	N		
Comments:						

Pdn 1/13/14

Reviewed By: Patrick Owen **Date:** 1-13-14

EPSOM SALT FILLING MACHINE: PERFORMANCE QUALIFICATION

C. Firmly Sealed: Verify That the Epsom Salt Filling Machine firmly seals the carton on both ends. Run the Epsom Salt Filling Machine for 4 hours while randomly sampling 25 cartons per hour for testing, for a total sample size of 100 cartons.

Firmly Sealed — Trial 2 of 4

Sample #	Is the top sealed? (Yes/No)	Is the top scorched? (Yes/No)	Is the bottom sealed? (Yes/No)	Is the bottom scorched? (Yes/No)	Verified By	Date
1	Y	N	Y	N		
2	Y	N	Y	N		
3	Y	N	Y	N		
4	Y	N	Y	N		
5	Y	N	Y	N		
6	Y	N	Y	N		
7	Y	N	Y	N		
8	Y	N	Y	N		
9	Y	N	Y	N	Patrick	1/13/14
10	Y	N	Y	N	Chris	
11	Y	N	Y	N		
12	Y	N	Y	N		
13	Y	N	Y	N		
14	Y	N	Y	N		
15	Y	N	Y	N		
16	Y	N	Y	N		
17	Y	N	Y	N		
18	Y	N	Y	N		
19	Y	N	Y	N		
20	Y	N	Y	N		
21	Y	N	Y	N		
22	Y	N	Y	N		
23	Y	N	Y	N		
24	Y	N	Y	N		
25	Y	N	Y	N		

Comments: PQ 1/13/14

Reviewed By: _____ **Date:** 1-13-14

EPSOM SALT FILLING MACHINE: PERFORMANCE QUALIFICATION

C. Firmly Sealed: Verify That the Epsom Salt Filling Machine firmly seals the carton on both ends. Run the Epsom Salt Filling Machine for 4 hours while randomly sampling 25 cartons per hour for testing, for a total sample size of 100 cartons.

Firmly Sealed						Trial 3 of 4	
Sample #	Is the top sealed? (Yes/No)	Is the top scorched? (Yes/No)	Is the bottom sealed? (Yes/No)	Is the bottom scorched? (Yes/No)	Verified By	Date	
1	Y	N	Y	N	Patrick Owen	1/13/14	
2	Y	N	Y	N			
3	Y	N	Y	N			
4	Y	N	Y	N			
5	Y	N	Y	N			
6	Y	N	Y	N			
7	Y	N	Y	N			
8	Y	N	Y	N			
9	Y	N	Y	N			
10	Y	N	Y	N			
11	Y	N	Y	N			
12	Y	N	Y	N			
13	Y	N	Y	N			
14	Y	N	Y	N			
15	Y	N	Y	N			
16	Y	N	Y	N			
17	Y	N	Y	N			
18	Y	N	Y	N			
19	Y	N	Y	N			
20	Y	N	Y	N			
21	Y	N	Y	N			
22	Y	N	Y	N			
23	Y	N	Y	N			
24	Y	N	Y	N			
25	Y	N	Y	N			
Comments:							

PGW 1/13/14

Reviewed By: [signature] Date: 1-13-14

EPSOM SALT FILLING MACHINE: PERFORMANCE QUALIFICATION

C. Firmly Sealed: Verify That the Epsom Salt Filling Machine firmly seals the carton on both ends.
Run the Epsom Salt Filling Machine for 4 hours while randomly sampling 25 cartons per hour for testing, for a total sample size of 100 cartons.

Firmly Sealed					Trial 4 of 4	
Sample #	Is the top sealed? (Yes/No)	Is the top scorched? (Yes/No)	Is the bottom sealed? (Yes/No)	Is the bottom scorched? (Yes/No)	Verified By	Date
1	Y	N	Y	N		
2	Y	N	Y	N		
3	Y	N	Y	N		
4	Y	N	Y	N		
5	Y	N	Y	N		
6	Y	N	Y	N		
7	Y	N	Y	N	PCM	1/13/14
8	Y	N	Y	N		
9	Y	N	Y	N		
10	Y	N	Y	N		
11	Y	N	Y	N		
12	Y	N	Y	N		
13	Y	N	Y	N		
14	Y	N	Y	N		
15	Y	N	Y	N		
16	Y	N	Y	N		
17	Y	N	Y	N		
18	Y	N	Y	N		
19	Y	N	Y	N		
20	Y	N	Y	N		
21	Y	N	Y	N		
22	Y	N	Y	N		
23	Y	N	Y	N		
24	Y	N	Y	N		
25	Y	N	Y	N		
Comments:						

PCM 1/13/14

Reviewed By: [signature] **Date:** 1-13-14

EPSOM SALT FILLING MACHINE: PERFORMANCE QUALIFICATION (Continued)

A. **Lot Code and Expiration Date Imprinting:** Verify that the lot code and expiration date numbers are imprinted properly and accurately.

Run the Epsom Salt Filling Machine for 4 hours while randomly sampling 25 cartons per hour for testing, for a total sample size of 100 cartons.

Lot Code and Expiration Date Imprinting			Trial 1 of 4	
Sample #	Is the Lot Code and Expiration Date visible? (Yes/No)	Is the Lot Code and Expiration Date correct? (Yes/No)	Verified By	Date
1	Y	Y		
2	Y	Y		
3	Y	Y		
4	Y	Y		
5	Y	Y		
6	Y	Y		
7	Y	Y		
8	Y	Y		
9	Y	Y		
10	Y	Y	[signature]	1/13/14
11	Y	Y		
12	Y	Y		
13	Y	Y		
14	Y	Y		
15	Y	Y		
16	Y	Y		
17	Y	Y		
18	Y	Y		
19	Y	Y		
20	Y	Y		
21	Y	Y		
22	Y	Y		
23	Y	Y		
24	Y	Y		
25	Y	Y		
Comments:				

[signature] 1/13/14

Reviewed By: [signature] Date: 1-13-14

EPSOM SALT FILLING MACHINE: PERFORMANCE QUALIFICATION (Continued)

A. Lot Code and Expiration Date Imprinting: Verify that the lot code and expiration date numbers are imprinted properly and accurately.

Run the Epsom Salt Filling Machine for 4 hours while randomly sampling 25 cartons per hour for testing, for a total sample size of 100 cartons.

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

PDW 1/13/14

Reviewed By: BVaughn Date: 1-13-14

EPSOM SALT FILLING MACHINE: PERFORMANCE QUALIFICATION (Continued)

A. **Lot Code and Expiration Date Imprinting:** Verify that the lot code and expiration date numbers are imprinted properly and accurately.

Run the Epsom Salt Filling Machine for 4 hours while randomly sampling 25 cartons per hour for testing, for a total sample size of 100 cartons.

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

PQS 1/13/14

Reviewed By: [signature] Date: 1-13-14

EPSOM SALT FILLING MACHINE: PERFORMANCE QUALIFICATION (Continued)

A. **Lot Code and Expiration Date Imprinting:** Verify that the lot code and expiration date numbers are imprinted properly and accurately.

Run the Epsom Salt Filling Machine for 4 hours while randomly sampling 25 cartons per hour for testing, for a total sample size of 100 cartons.

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

per 1/13/14

Reviewed By: [signature] Date: 1-13-14

EPSOM SALT FILLING MACHINE: PERFORMANCE QUALIFICATION (Continued)

A. Fill Weights: Verify that the fill weights are within the accepted range of (1.00+) or 2.00+ pounds (circle one).. Run the Epsom Salt Filling Machine for 4 hours while randomly sampling 25 cartons per hour for testing, for a total sample size of 100 cartons.

Fill Weights			Trial	1	of 4
Sample #	Actual Weight (Yes/No)	Acceptable (Yes/No)	Verified By	Date	
1	1.00	Y	Patrick Owen	1/13/14	
2	1.02	Y			
3	1.01	Y			
4	1.02	Y			
5	1.01	Y			
6	1.01	Y			
7	1.01	Y			
8	1.01	Y			
9	1.01	Y			
10	1.01	Y			
11	1.00	Y			
12	1.00	Y			
13	1.01	Y			
14	1.01	Y			
15	1.00	Y			
16	1.00	Y			
17	1.00	Y			
18	1.01	Y			
19	1.01	Y			
20	1.01	Y			
21	1.01	Y			
22	1.01	Y			
23	1.01	Y			
24	1.01	Y			
25	1.01	Y			

Comments:

Pat 1/13/14

Reviewed By: _____ **Date:** 1-13-14

EPSOM SALT FILLING MACHINE: PERFORMANCE QUALIFICATION (Continued)

A. Fill Weights: Verify that the fill weights are within the accepted range of (1.00+) or 2.00+ pounds (circle one).. Run the Epsom Salt Filling Machine for 4 hours while randomly sampling 25 cartons per hour for testing, for a total sample size of 100 cartons.

Fill Weights			Trial 2 of 4	
Sample #	Actual Weight (Yes/No)	Acceptable (Yes/No)	Verified By	Date
1	1.00	Y	Patrick Owen	1/13/14
2	1.00	Y		
3	1.00	Y		
4	1.00	Y		
5	1.00	Y		
6	1.00	Y		
7	1.01	Y		
8	1.01	Y		
9	1.01	Y		
10	1.00	Y		
11	1.02	Y		
12	1.01	Y		
13	1.02	Y		
14	1.02	Y		
15	1.01	Y		
16	1.02	Y		
17	1.02	Y		
18	1.02	Y		
19	1.02	Y		
20	1.02	Y		
21	1.02	Y		
22	1.02	Y		
23	1.02	Y		
24	1.01	Y		
25	1.01	Y		
Comments:				

PO 1/13/14

Reviewed By: [signature] Date: 1-13-14

EPSOM SALT FILLING MACHINE: PERFORMANCE QUALIFICATION (Continued)

A. Fill Weights: Verify that the fill weights are within the accepted range of (1.00+) or 2.00+ pounds (circle one).. Run the Epsom Salt Filling Machine for 4 hours while randomly sampling 25 cartons per hour for testing, for a total sample size of 100 cartons.

Fill Weights			Trial 3 of 4	
Sample #	Actual Weight (Yes/No)	Acceptable (Yes/No)	Verified By	Date
1	1.02	Y	Patrick Owen	1/13/14
2	1.02	Y		
3	1.02	Y		
4	1.02	Y		
5	1.03	Y		
6	1.02	Y		
7	1.02	Y		
8	1.02	Y		
9	1.03	Y		
10	1.03	Y		
11	1.02	Y		
12	1.02	Y		
13	1.03	Y		
14	1.03	Y		
15	1.02	Y		
16	1.02	Y		
17	1.02	Y		
18	1.02	Y		
19	1.02	Y		
20	1.02	Y		
21	1.01	Y		
22	1.02	Y		
23	1.02	Y		
24	1.02	Y		
25	1.02	Y		
Comments:				

Pat 1/13/14

Reviewed By: [signature] Date: 1-13-14

EPSOM SALT FILLING MACHINE: PERFORMANCE QUALIFICATION (Continued)

A. Fill Weights: Verify that the fill weights are within the accepted range of (1.00+) or 2.00+ pounds (circle one).. Run the Epsom Salt Filling Machine for 4 hours while randomly sampling 25 cartons per hour for testing, for a total sample size of 100 cartons.

Fill Weights			Trial	4	of 4
Sample #	Actual Weight (Yes/No)	Acceptable (Yes/No)	Verified By		Date
1	1.02	Y	Patt Owen		1/13/14
2	1.02	Y			
3	1.02	Y			
4	1.02	Y			
5	1.02	Y			
6	1.03	Y			
7	1.02	Y			
8	1.02	Y			
9	1.03	Y			
10	1.03	Y			
11	1.02	Y			
12	1.02	Y			
13	1.02	Y			
14	1.02	Y			
15	1.02	Y			
16	1.02	Y			
17	1.02	Y			
18	1.03	Y			
19	1.03	Y			
20	1.02	Y			
21	1.03	Y			
22	1.02	Y			
23	1.02	Y			
24	1.02	Y			
25	1.02	Y			
Comments:					

POS 1/13/14

Reviewed By: BVaught Date: 1-13-14

CALIBRATION VERIFICATION

Equipment	Serial #	Calibration Date	Calibration Due Date	Verified By	Date
Scale	565190359BM	12/19/13	1/31/14	PSR	1/13/14
Multimeter	100100221	At Factory	N/A	PSR	1/13/14

Reviewed By: B Walker **Date:** 1-13-14

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:			

Per 1/13/14

ATTACHMENT II. 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: _____

1/13/14

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
Patrick Owen	Engr. & Maint. Mgr	Patrick Owen	PGO	1/13/14
Brook Vaughn	QA Coordinator	Brook Vaughn	BV	1-13-14