

Validation Protocol

Title: Auto Poucher 6 IQ/OQ/PQ Final Report Number: E17-VAL-RFR-1010

Owner: Thomas Evans Revision: 0

Effective Date: May 1, 2017 Page: 1 of 21



Approvals

Signing below indicates agreement that the execution of the Installation, Operational, and Performance Qualification Protocol for Auto Poucher #6, Hayssen Ultima SV 12-19 HR, Serial # M352U89487, located at 109 Giles Place at the Giles Chemical Repackaging facility is complete and the process is validated.

Project Team Member	Functional Area	Signature	Date
Patrick Owen	Engineering	Tubbali	-4/27/17
Thomas Evans	Maintenance	Momes Evans	4/27/17
Monte Plott	Production	Monto Kuth	4/27/17
Matt Haynes	Operations	Chtha	4/28/17
Deborah Durbin	Quality	Murlin	4/27/17

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



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PRFMFR MAGNESIA, LLC

I. PURPOSE:

The purpose of the protocol is to certify with documented evidence that the Auto Poucher #6 (Hayssen Ultima SV 12-19 HR, Serial #: M352U89487, 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 Auto Poucher #6 located at Giles Chemical Repackaging Unit, 109 Giles Place, Waynesville, NC were all executed and all acceptance criteria were met.

II. SUMMARY

This Auto Poucher #6 (Hayssen Ultima SV 12-19 HR, Serial #: M352U89487) was manufactured by Hayssent Flexible Systems in Duncan, SC. It was installed at Giles in February of 2017. The machine is used to form, fill, and seal plastic film on a roll into a pouch, typically in 8 pound size.

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

The following tests were performed in this qualification:

 $Controls/Indicators\ Verification-to\ verify\ and\ document\ that\ the\ start/stop,\ emergency\ stop,\ and\ feed\ controls\ operate\ properly.$

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

Sealed pouch: Verification that the Auto Poucher #6 securely seals the pouch.

Fill Weights: Verification that Auto Poucher #6 is capable of producing a finished product that contains a weight of Epsom Salt with a minimum 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 Auto Poucher #6 (Hayssen Ultima SV 12-19 HR, Serial #: M352U89487) is installed, operating, and performing as expected. Auto Poucher #6 (Hayssen Ultima SV 12-19 HR, Serial #: M352U89487) is considered validated.

IV. RECOMMENDATIONS

 It is recommended that Auto Poucher #6 (Hayssen Ultima SV 12-19 HR, Serial #: M352U89487), located at Giles Chemical Repackaging, 109 Giles Place, Waynesville, NC 28786 be considered validated based on meeting the acceptance criteria of the IQ/OQ/PQ protocol.

V. REFERENCE:

E17-VAL-RIQ-1000, Auto Poucher6 IQ/OQ/PQ Protocol, rev 0, 2/28/2017



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Appendix I: INSTALLATION QUALIFICATION

A. Installation Qualification

01. Location

a. Verify that Auto Poucher #6 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 Auto Poucher #6 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
480V +/- 20V for Machine	482.2
480V +/- 20V for Scale	482.3
60 Hz	60
A compressed air line should be in place	Yes



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Appendix II: OPERATIONAL QUALIFICATION

1. Controls/Indicators Verification – to document that the Auto Poucher #6 operates as described.

Description	iption Function	
Controls On/Off	With line power to the machine turned on, the controls switch powers up the control panel	YES
Infeed	The infeed button on the control screen starts the process of feeding film through the rollers of the machine	YES
Emergency Stop	The emergency stop button stops the motion of the machine when pressed. It must be reset before the machine can be started again.	YES
Date Coder	Oder Verify that the date coder stamps a date code on the pouch as it indexes to the date code station.	
Scale	Scale Verify that when a pouch is presented into the forming tube at the fill station that the filler dumps a charge into the properly presented pouch.	
Sealer	Verify that the sealing station seals the filled pouch	



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Appendix III: PERFORMANCE QUALIFICATION

A. Firmly Sealed: Verify That the Auto Poucher #6 firmly seals the pouch.

Run the Auto Poucher #6 for 4 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 100 pouches.

Table I

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



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26	YES	YES	YES	NO
27	YES	YES	YES	NO
28	YES	YES	YES	NO
29	YES	YES	YES	NO
30	YES	YES	YES	NO
31	YES	YES	YES	NO
32	YES	YES	YES	NO
33	YES	YES	YES	NO
34	YES	YES	YES	NO
35	YES	YES	YES	NO
36	YES	YES	YES	NO
37	YES	YES	YES	NO
38	YES	YES	YES	NO
39	YES	YES	YES	NO
40	YES	YES	YES	NO
41	YES	YES	YES	NO
42	YES	YES	YES	NO
43	YES	YES	YES	NO
44	YES	YES	YES	NO
45	YES	YES	YES	NO
46	YES	YES	YES	NO
47	YES	YES	YES	NO
48	YES	YES	YES	NO
49	YES	YES	YES	NO
50	YES	YES	YES	NO



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



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76	YES	YES	YES	NO
77	YES	YES	YES	ИО
78	YES	YES	YES	МО
79	YES	YES	YES	NO
80	YES	YES	YES	NO
81	YES	YES	YES	NO
82	YES	YES	YES	NO
83	YES	YES	YES	NO
84	YES	YES	YES	NO
85	YES	YES	YES	NO
86	YES	YES	YES	NO
87	YES	YES	YES	NO
88	YES	YES	YES	NO
89	YES	YES	YES	NO
90	YES	YES	YES	NO
91	YES	YES	YES	NO
92	YES	YES	YES	NO
93	YES	YES	YES	NO
94	YES	YES	YES	NO
95	YES	YES	YES	NO
96	YES	YES	YES	NO
97	YES	YES	YES	NO
98	YES	YES	YES	NO
99	YES	YES	YES	NO
100	YES	YES	YES	NO



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PERFORMANCE QUALIFICATION (Continued)

B. Zipper Inserting: Verify that the zipper is inserted and is located correctly.
Run the Auto Poucher #6 for 4 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 100 pouches.

Table II-

Sample #	Is the Zipper inserted? (Yes/No)	Is the Zipper in correct location? (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



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Sample #	Is the Zipper inserted? (Yes/No)	Is the Zipper in correct location? (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



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Sample #	Is the Zipper inserted? (Yes/No)	Is the Zipper in correct location? (Yes/No) Yes	
51	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	



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Sample #	Is the Zipper inserted? (Yes/No)	Is the Zipper in correct location? (Yes/No) Yes	
76	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	



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PERFORMANCE QUALIFICATION (Continued)

A. Date Code Printing: Verify that the date code is printed properly and accurately.

Run the Auto Poucher #6 for 4 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 100 pouches.

Table II-

Sample #	Is the Date Code visible? (Yes/No)	Is the Date Code correct? (Yes/No) Yes	
1	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	



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Sample #	Is the Date Code visible? (Yes/No)	Is the Date Code correct? (Yes/No) Yes	
26	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	



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Sample #	Is the Date Code visible? (Yes/No)	Is the Date Code correct? (Yes/No) Yes	
51	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	



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Sample #	Is the Date Code visible? (Yes/No)	Is the Date Code correct? (Yes/No) Yes	
76	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	



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PERFORMANCE QUALIFICATION (Continued)

B. Fill Weights: Verify that the fill weights are within the accepted range of 8.00+ pounds (8.00 pounds minimum). Run the Auto Poucher #6 for 4 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 100 pouches.

Table III-

Sample #	Actual Weight	Acceptable (Yes/No)
1	8.04	YES
2	8.10	YES
3	8.02	YES
4	8.04	YES
5	8.04	YES
6	8.04	YES
7	8.05	YES
8	8.05	YES
9	8.06	YES
10	8.02	YES
11	8.04	YES
12	8.05	YES
13	8.03	YES
14	8.05	YES
15	8.05	YES
16	8.04	YES
17	8.05	YES
18	8.04	YES
19	8.05	YES
20	8.05	YES
21	8.10	YES
22	8.04	YES
23	8.03	YES
24	8.07	YES
25	8.04	YES



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Sample #	Actual Weight	Acceptable (Yes/No)	
26	8.03	YES	
27	8.07	YES	
28	8.04	YES	
29	8.04	YES	
30	8.09	YES	
31	8.06	YES	
32	8.08	YES	
33	8.01	YES	
34	8.08	YES	
35	8.07	YES	
36	8.06	YES	
37	8.08	YES	
38	8.07	YES	
39	8.03	YES	
40	8.06	YES	
41	8.05	YES	
42	8.02	YES	
43	8.01	YES	
44	8.05	YES	
45	8.04	YES	
46	8.07	YES	
47	8.05	YES	
48	8.03	YES	
49	8.05	YES	
50	8.05	YES	



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Sample #	Actual Weight	Acceptable (Yes/No)	
51	8.06	YES	
52	8.05	YES	
53	8.05	YES	
54	8.06	YES	
55	8.04	YES	
56	8.03	YES	
57	8.05	YES	
58	8.05	YES	
59	8.05	YES	
60	8.07	YES.	
61	8.06	YES	
62	8.03	YES	
63	8.05	YES	
64	8.06	YES	
65	8.06	YES	
66	8.03	YES	
67	8.04	YES	
68	8.03	YES	
69	8.04	YES	
70	8.04	YES	
71	8.07	YES	
72	8.05	YES	
73	8.06	YES	
74	8.06	YES	
75	8.05	YES	



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Sample #	Actual Weight	Acceptable (Yes/No)	
76	8.03	YES	
77	8.04	YES	
78	8.02	YES	
79	8.03	YES	
80	8.05	YES	
81	8.07	YES	
82	8.02	YES	
83	8.03	YES	
84	8.04	YES	
85	8.09	YES	
86	8.07	YES	
87	8.03	YES	
88	8.08	YES	
89	8.09	YES	
90	8.07	YES	
91	8.01	YES	
92	8.03	YES	
93	8.08	YES	
94	8.03	YES	
95	8.03	YES	
96	8.05	YES	
97	8.04	YES	
98	8.06	YES	
99	8.05	YES	
100	8.03	YES	



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Approvals

Signing below indicates agreement that the protocol is ready for execution of the Installation, Operational, and Performance Qualification for Hayssen Ultima SV 12-19 HR located at 109 Giles Place at the Packaging facility.

Project Team Member	Functional Area	Signature	Date
Patrick Owen	Engineering		
Thomas Evans	Maintenance		
Monte Plott	Production		
Matt Haynes	Operations		
Deborah Durbin	Quality		

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 Auto Poucher #6 (Hayssen Ultima SV 12-19 HR, Serial #: M352U89487), 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 Auto Poucher #6 located at Giles Chemical Repackaging Unit, 109 Giles Place, Waynesville, NC.

II. BACKGROUND:

This Epsom Salt Auto Poucher #6 was manufactured by Hayssen Flexible Systems in Duncan, SC. The machine was purchased by Giles in July of 2016. It was installed at Giles in February 2017. The machine is used to form, fill, and seal plastic film on a roll into a pouch, typically in 8 pound size.

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 the start/stop, emergency stop, and feed controls work properly.

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

Sealed pouch: Verification that Auto Poucher #6 securely seals the pouch (top, bottom, back)

Zipper insertion verification: Verification that Auto Poucher #6 properly inserts a zipper at the top of the pouch

Fill Weights: Verify that Auto Poucher #6 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. Auto Poucher #6 will form, fill, and top/bottom/back seal plastic rolled film stock into pouches with Epsom Salt. It is a 1 line system, forming, filling, and sealing 1 pouch at a time.
- B. Description of Operation
 - 01. A roll of pre-printed film stock is loaded onto the back of the machine. The film is threaded through a system of rollers that takes the film to the front of the machine.
 - 02. A spool of continuous zipper material is loaded onto a holder on the side of the machine near the back. The zipper material is threaded through a system of rollers that carries it perpendicular to the film. The zipper material is crushed, cut to length, and sealed onto the flat film. Only one side of the zipper flange is sealed to the film at this stage.
 - 03. The film then receives a lot code and expiration date. This is applied by a thermal transfer printer. The printer stamps the code onto the film while the film is stationary.
 - 04. The film advances to the forming tube which bends the flat film into a cylinder. The two edges are heat sealed together to form a tube of film in the shape of the pouch.
 - 05. The bottom of the tube is heat sealed during the creation of the previous pouch.
 - 06. A 16 head combination weigh scale mounted above the machine and integrated into the system weighs Epsom salt to the preset target weight specified in the recipe. It receives a fill request signal from the machine and drops the desired amount of Epsom salt into the tube.
 - 07. The machine heat seals and cuts the tube.
 - 08. The newly created filled pouch is dispensed onto an incline conveyor.
 - 09. The conveyor transports the pouch to packing.



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V. SCOPE

The Installation Operational Performance Qualification protocol is intended to certify with documented evidence that Auto Poucher #6 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
- 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 Auto Poucher #6 is installed as indicated by Hayssen.

Equipment/Materials

Auto Poucher #6, Hayssen Ultima SV 12-19 HR

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

Procedure

Perform each listed below for Auto Poucher #6.

• Location: Verify that the equipment is situated to allow sufficient room around the machine for access doors and panels to be opened.



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- Level: Verify instrument is level.
- Utilities
 - o 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 Auto Poucher #6 operates as indicated by Hayssen. The controls will be operated to test the ability of Auto Poucher #6 to provide adequate control for starting/stopping, pouch feed, and emergency stop.

Equipment/Materials

Auto Poucher #6, Hayssen Ultima SV 12-19 HR

Procedure

Test each operation of Auto Poucher #6

Acceptance Criteria

Verification that start/stop, infeed, and emergency stop controls function as indicated by operation manual

C. PERFORMANCE QUALIFICATION

Objective

The objective of performance testing is to document that Auto Poucher #6 performs the function required by Giles Chemical. The final product will be tested to verify:

- That Auto Poucher #6 firmly seals pouch (top, bottom, and back).
- That Auto Poucher #6 inserts a zipper at top of pouch.
- That the lot code and expiration date numbers are printed properly and accurately.
- That the fill weights are within the accepted range (8.0+ pounds for 8 pound pouches).

Equipment/Materials

Auto Poucher #6, Hayssen Ultima SV 12-19 HR

Empty Pouch(es) (for tare)

Scale

Procedure

Run Auto Poucher #6 on 8 pound pouches for 4 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 100 pouches.

Examine the finished product and check for:

- That Auto Poucher #6 firmly seals the pouch on top, bottom, and back.
- That Auto Poucher #6 inserts a zipper at top of pouch.
- That the lot code and expiration date numbers are printed properly and accurately.



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• That the fill weights are within the accepted range.

Acceptance Criteria

Auto Poucher #6 firmly seals the pouch on top, bottom, and back.

Auto Poucher #6 inserts a zipper at the top of the pouch.

Auto Poucher #6 correctly prints the lot code and expiration date.

That the fill weights are within the accepted range of 8.00+ pounds for 8 pound pouches.

VIII. CALIBRATION

Verify that all instrumentation that requires calibration is calibrated.

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

IX. REFERENCE:

Hayssen Ultima SV 12-19 HR Operation Manual



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AUTO POUCHER #6: INSTALLATION QUALIFICATION

A. Installation Qualification

01. Location

a. Verify that Auto Poucher #6 is positioned properly

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	R	4/24/17
The machine must be located in an area that is adequately ventilated	Yes	R	4/24/1

JE 4/24/17

02. Level

a. It is important to make sure that the Auto Poucher #6 is level.

Is the unit level? (Yes/No)	Acceptable (Yes/No)	Verified By	Date
Yes	Yes	R	4/24/17

R 4/24/17

03. Utilities

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

	UTILIES		
	Electrical		
Specified	Actual	Verified By	Date
480 V for Machine	482.2	R	4/24/17
220-240 V for Scale	482.3	R	4/24/17
60 Hz	60	R	4/24/11
	Air		
The machine requires compressed air.			
A compressed air line should be in place	Yes	R	4/24/1-
Comments:			

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Reviewed By:



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AUTO POUCHER #6: OPERATIONAL QUALIFICATION

B. Operation Qualification

01. Controls/Indicators Verification – to document that Auto Poucher #6 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 control switch powers up the control panel	Yes	R	4/24/17		
Infeed	The start button on the control screen starts the process of feeding film through the machine	405	R	4/24/17		
Emergency Stop	The emergency stop button stops the motion of the machine when pressed. It must be reset before the machine can be started again.	Yes	R	4/24/17		
Date Coder	Verify that the date coder puts a date code on the pouch as it indexes to the date code station.	Yes	R	4/24/17		
Dump Scale	Verify that when a pouch is presented to the fill station that the filler dumps a charge into the properly presented pouch.	Yes	R	4/24/17		
Sealer	Verify that the sealing station seals the filled pouch when it indexes into the seal station.	Ves	R	4/24/17		
Comments:						

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AUTO POUCHER #6: PERFORMANCE QUALIFICATION

C. Firmly Sealed: Verify that Auto Poucher #6 firmly seals the pouch.

Run Auto Poucher #6 for 4 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 100 pouches.

	Pouch Sealing			Trial /	of 4	
ample #	Is the top sealed? (Yes/No)	Is the bottom sealed? (Yes/No)	Is the back sealed? (Yes/No)	Do any of the seals leak? (Yes/No)	Verified By	Date
1	Yes	Yes	Yes	N.	12	4/24/17
2	Yes	Yes	Yes	N,	R	4/24/17
3	Yes	Yes	Yes	No	12	4/24/17
4	Yes	Yes	Yes	N.	12	4/24/17
5	yes	Yes	Yes	No	R	4/24/17
6	Yes	Yes	Yes	No	13	4/24/11
7	Yes	Yes	Yes .	N.	R	4/24/17
8	Yes	Yes	Yes	N	18	4/24/17
9	Yes	Yes	Yes	N.	12	1/24/17
10	Yes	Yes	Yes	n.	73	4/24/17
11	Yes	Ye	Yes	N.	13	4/24/17
12	Yes	Yes	Yes	No	13	4/24/17
13	Yes	Yes	Yes	No	1/2	4/24/17
14	Yes	Yes	Yes	N,	1/2	4/24/17
15	Yes	Yes	Yes	N	R	4/24/17
16	405	Yes	Yes	N.	M	4/24/12
17	Yes	Yes	Yes	N,	1/2	4/24/17
18	Yes	Yes	Yes	No	1/2	4/24/17
19	Yes	Yes	Yes .	N.	1/2	4/24/17
20	Yes	Yes	<u>Yes</u>	No	1/2	4/24/17
21	Yes	Yes	les	No	02	4/24/17
22	Yes	Yes	Yes	No	1/2	4/24/17
23	Yes	Yes	Yes	N.	1/2	4/24/17
24	Yes	Yes	Yes	No	K	4/24/12
25	Yes	Yes	Yes	N,	1/2	4/24/17
Co	mments:					

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AUTO POUCHER #6: PERFORMANCE QUALIFICATION

C. Firmly Sealed: Verify that Auto Poucher #6 firmly seals the pouch.

Run Auto Poucher #6 for 4 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 100 pouches.

pouches.		Pou	ich Sealing		Trial 2	of 4
Sample #	Is the top sealed? (Yes/No)	Is the bottom sealed? (Yes/No)	Is the back sealed? (Yes/No)	Do any of the seals leak? (Yes/No)	Verified By	Date
1	Yes	Yes	Yes	No	The	4/24/17
2	Yes	Yes	Yes	n.	R	4/24/17
3	Yes	Yes	Yes	No	R	4/24/17
4	Yes	Yos	Yes	N.	1/2	4/24/17
5	Yes	Yex	Yes	N	R	4/24/17
6	Yes	Yer	Yes	No	R	4/24/12
7	Yes	Yer	Yes	No	Th.	4/24/12
8	Yes	Yes	Yes	N,	R	4/24/17
9	Yes	Yes	Yes	No	R	4/24/17
10	Yes	Ves	Yes	N.	The state of the s	4/24/17
11	4.15	Yes	Yes	No	R	4/24/17
12	Yes	Yes	Yes	No	The	4/24/17
13	Ves	Yes	Yes	No	Ph	4/24/17
14	Yes	Yes	Yes	ns	The	4/24/11
15	Yes	Yes	Yes .	No	R	4/24/17
16	Yes	Yes	Yes	W.	B	4/24/17
17	Yes	Yes	Yes	N.	R	4/24/17
18	Yes	1/es	//es	N.	R	4/24/12
19	Yes	Yes	Yar	No	The	4/24/1-
20	Yes	Yes .	Yes	No	1/2	4/24/17
21	les	Yes	Yes	No	1/2	4/24/17
22	Yes	Yes	Ker	No	1/2	4/24/17
23	Yes Yes	les	Ves	N.	The state of the s	4/24/17
24	Ves	1/es	Yes	Ns.	K	4/24/17
25	Yes	les	Yes	No	X	4/24/17
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AUTO POUCHER #6: PERFORMANCE QUALIFICATION

C. Firmly Sealed: Verify that Auto Poucher #6 firmly seals the pouch.

Run Auto Poucher #6 for 4 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 100

pouches.		Por	uch Sealing		Trial 3	of 4
Sample #	Is the top sealed? (Yes/No)	Is the bottom sealed? (Yes/No)	Is the back sealed? (Yes/No)	Do any of the seals leak? (Yes/No)	Verified By	Date
1	Yer	Yes	Yes	No	R	4/24/17
2	Yes	Yes	Yes	No	R	4/24/17
3	Yes	Yes	Yes	Ns	1/2	4/24/17
4	Yes	Yes	Yes	No	R	4/24/17
5	Yes	Yes	Yes	Ns	JE.	4/24/17
6	Yes	Yes	Yes	No.	1/2	4/24/17
7	Yes	Yes	Yer	No	1/2	4/24/11
8	Yes	Yes	Yes	No.	1h	4/24/17
9	Yes	Yes	Yes	No	The state of the s	4/24/17
10	Yes	Yes	Yes	No No No	1/2	4/24/1
11	Yes	les	Yes	No	15	4/24/17
12	Yes	Yes	1/es	No	1/2	4/24/17
13	Yes	Yes	Yes	No	The state of the s	4/24/17
14	Yes	Ves	1/es	No	The	4/24/17
15	Yes	Yes	Yes	No	K	4/24/17
16	Yes	les	Kes	No	The	4/24/17
17	Yes	Fes	Yes	n	JE.	4/24/17
18	Yes	les	Yes	74	R	4/24/17
19	Yes	Yes	Yes	Ns	1/2	4/24/17
20	Yes	Yes	4es	N.	1/2	4/24/17
21	Yes	Yes	Yes	N.	Br	4/24/17
22	Yes	Yes	1/es	K	1/2	4/24/17
23	Yes	Yes	1/es	No	1/2	4/24/17
24	Yes	Yes	Yes	No	1/2	4/24/17
25	les .	Yes	Yes	No	P2	4/24/17
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AUTO POUCHER #6: PERFORMANCE QUALIFICATION

C. Firmly Sealed: Verify that Auto Poucher #6 firmly seals the pouch.

Run Auto Poucher #6 for 4 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 100 pouches.

pouches		Pou	ch Sealing		Trial 4	of 4
Sample #	Is the top sealed? (Yes/No)	Is the bottom sealed? (Yes/No)	Is the back sealed? (Yes/No)	Do any of the seals leak? (Yes/No)	Verified By	Date
1	Yes	Yes	Yes	No	J.	4/24/17
2	Yes	Yes	Yes	No	B	4/24/1
3	Yes	Yes	Yes	n.	H	4/24/17
4	Ves	Yes	Yes	No	R	4/24/17
5	Yes	Yes	Yes	N.	H	4/24/17
6	Yes	Yes	Yes	n,	R	4/24/12
7	Yes	Yes	/er	N,	13	4/24/17
8	Yes	Yes	leg	14	R	4/24/17
9	Yes	Yes	Yes	N.	1/2	4/24/17
10	405	Yes	Yes	No	R	4/24/17
11	Yes	Yes	Ver	N.	R	4/24/17
12	Yes	Yes	Yes	No	R	4/24/17
13	Yes	Yes	Yes	No	R	4/24/11
14	Yes	Yes	Yer	No	12	4/24/17
15	Yes	Yes	Ves	No No	1/2	4/24/17
16	Yes	Yes	Yes	N	12	4/24/17
17	Yes	Yes	Yes	Ws	1/2	4/24/11
18	Yer	Yes	Yes	N	1/2	4/24/17
19	Yes	Yes	Yes	No	1/2	4/24/17
20	Yes	les	Yes	n	1/E	4/24/12
21	Ves	Yes	Yes	n.	1/2	4/24/17
22	·	Yes	Yes	N,	He	4/24/17
23	Yes Yes	Yes	les	N	1/2	4/24/17
24	Yes	Yes	1/20	No	H	4/24/17
25	Yes	Yes	Yer	No	K	4/24/17
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AUTO POUCHER #6: PERFORMANCE QUALIFICATION (Continued)

D. Zipper Inserting: Verify that the zipper is inserted and is located correctly.

Run the Auto Poucher #6 for 4 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 100 pouches.

pouches.	Zipper Ins		Trial	/ of 4
Sample #	Is the Zipper inserted? (Yes/No)	Is the Zipper in correct location? (Yes/No)	Verified By	Date
1	Yer	Yes	R	4/24/17
2	Yes	Yes	R	4/24/17
3	Yes	Yes	R	4/24/17
4	Yes	Yes	R	4/24/12
5	Yes	Yes	R	4/24/17
6	405	Yes	R	4/24/17
7	Yes	Yes	R	4/24/19
8	Yes	Yes	R	4/24/17
9	Yes	Yes	R	4/24/17
10	Yes	Yes	R	4/24/17
11	Yes	Yes	R	4/24/17
12	Yes	Yes	R	1/24/17
13	Yes	Yes	K	4/24/12
14	Yes	Yes	Pr	4/24/17
15	Yes	Yes	R	4/24/17
16	Yes	Yes	K	4/24/17
17	Yes	Yes	K,	4/24/17
18	Yes	Yes	K,	4/24/17
19	Yes	Yes	K	4/24/17
20	Yes	Yes	K	4/24/17
21	Yes	Yes .	Z	4/24/17
22	Yes	Yes	7	4/24/17
23	Yes	tes	14	4/24/17
24	Yes .	Ver	R	4/24/17
25	Ves	Yes	Z	4/24/17
Comments				

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AUTO POUCHER #6: PERFORMANCE QUALIFICATION (Continued)

D. Zipper Inserting: Verify that the zipper is inserted and is located correctly.

Run the Auto Poucher #6 for 4 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 100 pouches

Zipper Inserting			Trial	2 of 4	
Sample #	Is the Zipper inserted? (Yes/No)	Is the Zipper in correct location? (Yes/No)	Verified By	Date	
1	Yes	Yes	R	4/24/17	
2	4es	Yes	R	4/24/17	
3	Yes	Yes	R	4/24/17	
4	Yes	Yas	R	4/24/11	
5	Yes	Yes	R	4/24/12	
6	Yes	Yes	R	4/24/17	
7.	Yes	Yes	R	4/24/17	
8	Yer	Yes	The state of the s	4/24/17	
9	Yes	les	R	4/24/17	
10	les .	Yes	Th	4/24/17	
11	Yes	Yes	K	4/24/17	
12	Yes	Yes	/E	4/24/17	
13	Yes	<i>Yes</i>	R	4/24/11	
14	Yes	Yex	The	4/24/17	
15	Yes	Yes	1/2	4/24/1	
16	Yes	Yer	H_	4/24/17	
17	Ves	Yes	R	4/24/17	
18	l/es	l'es .	1/2	4/24/17	
19	les .	Yes	1/2	4/24/17	
20	Yes	Yes	R	4/24/17	
21	Yes	Yes	<u> </u>	4/24/17	
22	Yes	Yes	K	4/24/12	
23	les	Yes	R	4/24/1-	
24	Yes	Yer	1	4/24/1	
25	Ker	Yes	12	4/24/17	
Comments:					

Reviewed By: Date: 4-24-17

Controlled Document



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AUTO POUCHER #6: PERFORMANCE QUALIFICATION (Continued)

D. Zipper Inserting: Verify that the zipper is inserted and is located correctly.

Run the Auto Poucher #6 for 4 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 100 pouches.

	Zipper Ins	erting	Trial	3 of 4
Sample #	Is the Zipper inserted? (Yes/No)	Is the Zipper in correct location? (Yes/No)	Verified By	Date
1	Yes	Yes	R	4/24/17
2	Yes	Yes	Th	4/24/17
3	Yes	Yes	R	4/24/17
4	4es	Yes	R	4/24/17
5	Yes	Yes	R	4/24/17
6	Yes	Yes	_h_	4/24/17
7	Yes .	Yes	R	4/24/17
8	Yes	Yes	B	4/24/17
9	Yes	Yes	R_	4/24/17
10	Yes	Yer	K	4/24/17
11	<i>Yes</i>	Ver	The	4/24/17
12	Yes	les	K	4/24/17
13	Ves .	Yes	R	4/24/17
14	Yes	Yer	K	4/24/17
15	Ver	Yes	The	4/24/17
16	l'es .	Yes	1/2	4/24/1
17	Yes	Yes	Jr.	4/24/17
18	Yes	. Kes	The	4/24/17
19	Yes	Yes	1/2	4/24/17
20	Ves	Kes	1/2	4/24/0
21	Yes	Kes	R	4/24/1-
22	Yes	Ves	1/2	4/24/17
23	les	Yes	1/2	4/24/17
24	Yes Yes Yer	Yes Yos Yes	Æ	4/24/17
25	Yes .	Kes	1/2	4/24/17
Comments			,	

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Date:

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AUTO POUCHER #6: PERFORMANCE QUALIFICATION (Continued)

D. Zipper Inserting: Verify that the zipper is inserted and is located correctly.

Run the Auto Poucher #6 for 4 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 100 pouches.

	Zipper Ins	the second secon	Trial	4 of 4
Sample #	Is the Zipper inserted? (Yes/No)		Verified By	Date
1	Yes	Yes	B	4/24/12
2	Yes	Yes	R	4/24/12
3	Yes	Yes	R	4/24/17
4	Yes	Yes	R	14/24/12
5	Yes	Ves .	Z	4/24/12
6	Yes	Yes	K	4/24/17
7	Yes	Yes	K	4/21/12
8	Yes	Yes	The	4/24/17
9	Yes	les	K	4/24/17
10	<i>Yes</i>	Yes	The	4/24/17
11	l'es	Yes	The	1/24/17
12	Yes	Yes	L.	4/24/17
13	les	Yes	Re	4/24/17
14	Yes	Kes	R	4/24/17
15	Yes	Yes	The	4/24/17
16	Yes	les	the	4/24/17
17	Yes	Yes	1/2	4/24/12
18	Yes	Yes	The	4/24/12
19	405	Yes	R	4/24/12
20	Yes	Yes	Th	1/24/17
21	. Yes	Yes	The	4/24/12
22	Yes	Yes	The	4/24/15
23	Yes	Yes	The	4/24/17
24	Yes	Yes	K	4/24/17
25	l'es .	Yes Yes Yes	1/2	4/24/17
Comments:				

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Date:



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AUTO POUCHER #6: PERFORMANCE QUALIFICATION (Continued)

E. Date Code Printing: Verify that the date code is printed properly and accurately.

Run the Auto Poucher #6 for 4 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 100 nouches

	Lot Code and Expiration		Trial	/ of 4
Sample #	Is the Date Code visible? (Yes/No)	Is the Date Code correct? (Yes/No)	Verified By	Date
1	Ves	Yer	R	4/24/17
2	Yes	Yes	1/2	4/24/17
3	Yes	Yes	1/2	4/24/17
4	Yes	Yes	K	4/24/17
5	Yes	Yes	H	4/24/17
6	Yes	Yes	K	4/24/17
7	Yes	Yes	Jk.	4/24/19
8	Ves	Yes	K	4/24/17
9	<i>lles</i>	Yes	Z	4/24/17
10	Yes	Yes	The	4/24/17
11	Yes	Yes	Je	4/24/17
12	Yes	. Yes	The state of the s	4/24/17
13	Yes	Yes	H	4/24/17
14	Yes	Yes	1/2	4/24/n
15	Yes	Yes	F2	4/24/17
16	l'e	Ves	h	4/24/17
17	Yes	Ves	1/2	4/24/17
18	Yes	Yes	1/2	4/24/17
19	l'es	Yes	4	4/24/17
20	Yes	Yes	1/2	4/24/17
21	Yes	Yes	1/2	4/24/17
22	Yes	Yes	1/2	4/24/17
23	Yes	Yes	1/2	4/24/17
24	Yes Yes Yes	Ves	R	4/24/17
25	Yes	Yes	K	4/24/17
Comments				

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Reviewed By:

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Date:



Validation Protocol

Title: Auto Poucher 6 IQ/OQ/PQ Protocol Number: E17-VAL-RIQ-1000

Owner: Thomas Evans Revision: 0

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AUTO POUCHER #6: PERFORMANCE QUALIFICATION (Continued)

E. Date Code Printing: Verify that the date code is printed properly and accurately.

Run the Auto Poucher #6 for 4 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 100 pouches.

	Lot Code and Expiration		Trial	2 of 4
Sample #	Is the Date Code visible? (Yes/No)	Is the Date Code correct? (Yes/No)	Verified By	Date
1	Ves	Yes	1/2	4/4/12
2	Yes	Yes	The state of the s	4/24/12
3	Ves	Yes	1/2	4/24/12
4.	Yes	Yes	1/2	4/24/12
5	Yes	Yes	R	4/24/12
6	Yes	Yes	1/2	4/24/12
7	Ves	Ves	K	4/24/12
8	Yes	Yes	1/2	4/24/17
9	Yes	Yes	R	4/24/17
10	Yes	Yes	R	4/24/17
11	Yes	Yes	R	4/24/17
12	Yes	Ves	h	4/24/11
13	Yes	Yes	R	4/24/17
14	Yes	Yes	R	4/24/17
15	Yes	Yes	R	4/24/17
16	Yes	Yes	R	4/24/17
17	Yes	les	J2	1/24/17
18	Yes	les	K	4/24/0
19	Yes	Yes	R	4/24/17
20	Yes	Yes	h	4/24/17
21	Yes	Yes	h	4/24/17
22	Yes	les	B.	4/24/17
23	Yes	Yer	1/2	4/24/17
24	Yes	Ves	Jr_	4/24/17
25	Yes	Yes	1 Ja	4/24/17
Comments				

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Reviewed By:

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Date:



Validation Protocol

Title: Auto Poucher 6 IQ/OQ/PQ Protocol Number: E17-VAL-RIQ-1000

Owner: Thomas Evans Revision: 0

Effective Date: February 28, 2017 Page: 11 of 16



AUTO POUCHER #6: PERFORMANCE QUALIFICATION (Continued)

E. Date Code Printing: Verify that the date code is printed properly and accurately.

Run the Auto Poucher #6 for 4 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 100 pouches.

	Lot Code and Expiration I	The state of the s	Trial	3 of 4
Sample #	Is the Date Code visible? (Yes/No)	Is the Date Code correct? (Yes/No)	Verified By	Date
1	Yes	Yes .	Th.	4/24/17
2	405	Yes	1/2	4/24/1
3	Yes	Yes	1/2	4/24/17
4	Yes	Yes	R	4/24/17
5	Yes	Yes	B	4/24/17
6	Yes	Yes	K	4/24/17
7	Yes	Yes	1/2	4/24/12
8	Yes	Yes	The state of the s	4/24/17
9	Yes	Yes	The.	4/24/17
10	Yes	les	1/2	4/24/17
11	Yes	Yes	1/2	4/24/17
12	Yes	Yes	The state of the s	4/24/17
13	Yes	Yes	1/2	4/24/17
14	Ves	Lo	B	4/24/17
15	les .	Ves	h	4/24/17
16	Yes	Ves	h	1/24/17
17	Yes	Yas	K	4/24/10
18	Yes	Ves	B	4/24/17
19	Yes	Yes	B	4/24/17
20	Yes	Yes	1/2	4/24/17
21	Yes .	Ves	1/2	4/24/17
22	Yes	. Yes	h	4/24/17
23	les	Ves	The	4/24/17
24	Yes Yes	Ves	12	4/24/17
25	Ves	Yes	3	4/24/12

	1 1 . 2 1			4/24/1
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Validation Protocol

Title: Auto Poucher 6 IQ/OQ/PQ Protocol Number: E17-VAL-RIQ-1000

Owner: Thomas Evans Revision: 0

Effective Date: February 28, 2017 Page: 11 of 16



AUTO POUCHER #6: PERFORMANCE QUALIFICATION (Continued)

E. Date Code Printing: Verify that the date code is printed properly and accurately.

Run the Auto Poucher #6 for 4 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 100 pouches.

CONTRACTOR OF THE PROPERTY OF THE PARTY OF T	Lot Code and Expiration	Date Imprinting	Trial	4 of 4
Sample #	Is the Date Code visible? (Yes/No)	Is the Date Code correct? (Yes/No)	Verified By	Date
1	Yes	Yes	1	Martin
2	Yes	Yes	16	1/24/17
3	Yes	Yes	1	4/24/1)
4	Yes	Yes	73	1/2/19
5	Yes	Yes	7/2-	1/20/19
6	Yes	Yes	13	4/24/1
7	Yes	Yes	73	4/24/1
8	Yes	Yes	16	4/21/12
9	Yes	Yes	16	21/21/10
10	1/es	Yes	14	1/24/12
11	Yes	Yes	1/2	1/24/12
12	Yes	Yes	13	4/24/12
13	Yes	Yes	B	4/24/12
14	Yes	les	1/2	4/24/12
15	Yes	Ves	K	4/24/1
16	Yes	Yes	1/2	4/24/12
17	Yes	Yes	1/2	4/24/12
18	Yes	l'es	1/2	4/24/12
19	Yes	Yes	1/2	4/24/12
20	Yes	Yes	The	4/24/12
21	Yes	Yes	1/L	4/24/17
22	Ves	Yes	K	4/24/12
23	les	<i>Yes</i>	1/2	4/24/12
24	Yes	Yes	The	8/24/17
25	Ves	Yes	1/2	4/24/17
Comments:				

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Date:



Validation Protocol

Title: Auto Poucher 6 IQ/OQ/PQ Protocol Number: E17-VAL-RIQ-1000

Owner: Thomas Evans Revision: 0

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AUTO POUCHER #6: PERFORMANCE QUALIFICATION (Continued)

F. Fill Weights: Verify that the fill weights are within the accepted range of 8.00+ Pounds.

Run the Auto Poucher #6 for 4 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 100 pouches.

	Fill W	eights	Trial	/ of 4
Sample #	Actual Weight (Yes/No)	Acceptable (Yes/No)	Verified By	Date
1	8,04	Yes	18	4/24/17
2	8.10	4.05	R	4/24/17
3	8,02	Yes	R	4/24/17
4	8.64	Yes	R	4/24/17
5	8,04 8,04 8,05 8,05	Yes	R	4/24/11
6	8,04	Yes	R	4/24/17
7	8, 05	Yes	Nr.	4/24/17
8	8,05	Yes	H H	4/24/12
9	8,06	Yes	R	4/24/17
10	8.02	Yes	82	4/24/17
11	8.04	Yes	R	4/24/17
12	8.05	Yes	R	4/24/17
13	8.03	Yes	R	4/24/17
14	8.05	Yes	R	4/24/17
15	8.05	tes	The	4/24/17
16	8.04	Yes	H	4/24/17
17	8.05	Yes	K K	4/24/17
18	8.04	Yes	K	4/24/17
19	P. 05	405	The The	4/24/17
20	8.05	Yes	1/2	4/24/17
21	8.10	Yes	H	4/24/17
22	8.04	Yes	IL,	4/24/17
23	8.03	Yes	1/2	4/24/17
24	8.07	Yes	1/2	4/24/17
25	8.04	Yes	1/2	4/24/17
Commen	S:			

23	4/24/1
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Validation Protocol

Title: Auto Poucher 6 IQ/OQ/PQ Protocol Number: E17-VAL-RIQ-1000

Owner: Thomas Evans Revision: 0
Effective Date: February 28, 2017 Page: 12 of 16



AUTO POUCHER #6: PERFORMANCE QUALIFICATION (Continued)

F. Fill Weights: Verify that the fill weights are within the accepted range of 8.00+ Pounds.

Run the Auto Poucher #6 for 4 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 100 pouches.

	Fill V	/eights	Trial	2 of 4
Sample #	Actual Weight (Yes/No)	Acceptable (Yes/No)	Verified By	Date
1	8.03	Yes	13	4/24/17
2	8.07	Yes	B	4/24/17
3	8.04	Yes	R	4/24/17
4	8.04	Yes	13	4/24/17
5	8.09	Yes	B	4/24/17
6	8.06	Yes	R	4/24/17
7	8.08	Yes	R	4/24/17
8	8.01	Yes	1/2	4/24/17
9	8.08	Yes	R	4/24/17
10	8.07	Yes		4/24/17
11	8,06	Yes	He H	4/24/17
12	8.08	Yes	R	4/24/17
13	8,07	Yes	1/2	4/24/11
14	8,03	Yes	The state of the s	4/24/17
15	8.06	Yes	1/2	4/24/17
16	8.05	Yes	R	4/24/17
17	8,02	Yes	Th	4/24/17
18	8.01	Yes	R	4/24/17
19	8.05	Yes	12	4/24/17
20	8.04	Yes	1/2	4/24/17
21	8.07	Yes	18	4/24/17
22	8.05	Yes	1/2	4/24/17
23	8.03	Yes	The state of the s	4/24/17
24	8.05	Yes	Sk	4/24/17
25	8.05	Yes	20	4/24/17
Comment	s:			

Artiful Date: 4-24-17

Controlled Document



Validation Protocol

Title: Auto Poucher 6 IQ/OQ/PQ Protocol

Number: E17-VAL-RIQ-1000 Revision: 0

Owner: Thomas Evans Effective Date: February 28, 2017

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AUTO POUCHER #6: PERFORMANCE QUALIFICATION (Continued)

F. Fill Weights: Verify that the fill weights are within the accepted range of 8.00+ Pounds. Run the Auto Poucher #6 for 4 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 100 pouches.

	Fill W	'eights	Trial	3 of 4
Sample #	Actual Weight (Yes/No)	Acceptable (Yes/No)	Verified By	Date
1	8.06	Yes .	\mathcal{M}	רואנועו
2	8.05		17.	11/21/12
3	8,05	Yes	B	4/21/10
4	8.06	Yes	13	4/24/1
5	8.06	Yes	133	Abula
6	8.03	Yes	1	4/24/1
7	8.65	Yes	13	4/24/1
8	8.05	Yes	R R R K	4/24/17
9	8.05	Yes	1	4/24/12
10	8.07	Yes	The state of the s	4/24/12
11	8.06	Yes	1	4/34/12
12	8.03	Yes	12	4/24/12
13	8.05	Yes	12	4/24/12
14	8.06	Yes	Th	4/24/12
15	8.06	Yes	The	4/24/12
16		Yes	Th	4/24/10
17	8.04	Yes	N	4/24/12
18	8.03	Yes	1/2	4/24/17
19	8.04	Yes	1/2	4/24/17
20	8.04	Yes	1/2	4/24/17
21	8.07	Yes	1/4	4/24/17
22	8.05	Yes	The	4/24/17
23	8.06	Yes Yes	The .	4/24/17
24	8.06 8.06 8.05	Yes	1/2	4/24/17
25	8.05	Yes	M	4/24/17
Comment	1			

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Reviewed By:

Date:



Validation Protocol

Title: Auto Poucher 6 IQ/OQ/PQ Protocol Number: E17-VAL-RIQ-1000

Owner: Thomas Evans Revision: 0

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AUTO POUCHER #6: PERFORMANCE QUALIFICATION (Continued)

F. Fill Weights: Verify that the fill weights are within the accepted range of 8.00+ Pounds. Run the Auto Poucher #6 for 4 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 100 pouches.

	Fill Weights Trial			4 of 4
Sample #	Actual Weight (Yes/No)	Acceptable (Yes/No)	Verified By	Date
1	8,03	<u>Yes</u>	12	4/24/12
2	8.04	Yes	12	4121110
3	8.02	Yes	72	4/24/17
4	8.03	1/25	13	4/24/12
5	8.02 8.03 8.05	Yes	13	4/20/10
6	8.07	Yes	R	41)11/10
7	8.02	Yes	23	4/2/1/10
8	8.03	Yes	7/	4/20/17
9	8.04	Yes	73	4/24/17
10	8.09	Yes	12	4/20/10
11	8.07	Yes	73	4/24/11
12	8.03	Yes	12	4/24/12
13	8.08	Yes	3	4/24/12
14	8.09	Yes	77	4/24/11
15	8.07	Yes	The	4/24/11
16	8.01	Yes	The state of the s	4/24/12
17	8.03	Yes	1/2	4/24/12
18	8.68	Yes	1/2	4/24/12
19	8.03	Yes	26	4/24/12
20	8.63	Yes	2	4/24/12
21	8, 45	Yes	1/2	4/24/12
22	8.04	Yer	The state of the s	4/24/17
23	8.06 8.05	les	18	4/24/17
24	8.05	Yes	R	4/24/17
25	8.03	Yes	The state of	4/24/12
omments:				

Reviewed	Ву:
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Date:



Validation Protocol

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Owner: Thomas Evans Revision: 0

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CALIBRATION VERIFICATION

Equipment	Serial #	Calibration Date	Calibration Due Date	Verified By	Date
Scale	B652507726	3/29/17	4/28/17	R	4/24/17
Multimeter	100100221	at Manufacture	N/A	R	4/24/17

Reviewed By:	Molate 19-	Date:	4-24-17	
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Validation Protocol

Title: Auto Poucher 6 IQ/OQ/PQ Protocol Number: E17-VAL-RIQ-1000

Owner: Thomas Evans

Effective Date: February 28, 2017 Page: 14 of 16

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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
	No.		
	No. Co.		
Comments:			

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Validation Protocol

Title: Auto Poucher 6 IQ/OQ/PQ Protocol

Effective Date: February 28, 2017

Number: E17-VAL-RIQ-1000 Revision: 0

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ATTACHMENT II. PROTOCOL DEVIATION REPORT (PDR)

Owner: Thomas Evans

		General Information
System	Name:	Protocol Number:
		Protocol Step & Page No.:
		Instructions
1.	The validation specialist assig For example, 001, 002, etc. ca	ns a sequential report number for each deviation with a specific protocol. n be easily referenced in a report.
2.	Reference the relevant protoco	number, step and page number of the noted deviation above.
3.	Complete the below listed sec	tions. If necessary, use additional pages and attach any supporting info.
4.	Include the original PDR(s) w Report.	ith the protocol as an attachment. Summarize the impact of the deviation in the Validation
Descrip	tion of Deviation:	Notus No 4/24/17
Investig	ation Evaluation and Results:	
Correcti	ve Action and Resolution:	
Overall	Investigation Review:	
Prepareo	I By:	Date:



Validation Protocol

Title: Auto Poucher 6 IQ/OQ/PQ Protocol

Effective Date: February 28, 2017

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Owner: Thomas Evans

Revision: 0

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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
Thomas Evans	Engineere Mainterance	Thoma Evas	R	4/24/17
Robert Elic Deuns	Engineers Mainterace	holaly	RED	4-24-17
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			,	
		~		
		V TABLE		