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		4/27/17
Thomas Evans	Maintenance		4/27/17
Monte Plott	Production		4/27/17
Matt Haynes	Operations		4/28/17
Deborah Durbin	Quality		4/27/17

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 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

1. 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

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

Appendix II: OPERATIONAL QUALIFICATION

1. **Controls/Indicators Verification** – to document that the Auto Poucher #6 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
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	Verify that the date coder stamps a date code on the pouch as it indexes to the date code station.	YES
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.	YES
Sealer	Verify that the sealing station seals the filled pouch when it indexes into the seal station	YES

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

APPENDIX III TABLE I CONTINUED

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)
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

APPENDIX III TABLE I CONTINUED

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

APPENDIX III TABLE I CONTINUED

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)
76	YES	YES	YES	NO
77	YES	YES	YES	NO
78	YES	YES	YES	NO
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

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

APPENDIX III TABLE II CONTINUED –

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

APPENDIX III TABLE II CONTINUED –

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

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)
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 Date Code visible? (Yes/No)	Is the Date Code 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 Date Code visible? (Yes/No)	Is the Date Code 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 Date Code visible? (Yes/No)	Is the Date Code 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)

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

APPENDIX III TABLE III CONTINUED -

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

APPENDIX III TABLE III CONTINUED -

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

APPENDIX III TABLE III CONTINUED -

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

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.

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
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 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.

- 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 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.

- 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

AUTO POUCHER #6: INSTALLATION QUALIFICATION

A. Installation Qualification

01. Location

a. Verify that Auto Poucher #6 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	JE	4/24/17
The machine must be located in an area that is adequately ventilated	Yes	JE	4/24/17
Comments:			

JE 4/24/17

02. Level

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

LEVEL			
Is the unit level? (Yes/No)	**Acceptable (Yes/No)**	**Verified By**	**Date**
Yes	Yes	JE	4/24/17
Comments:			

JE 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	JE	4/24/17
220-240 V for Scale	482.3	JE	4/24/17
60 Hz	60	JE	4/24/17
Air			
The machine requires compressed air.			
A compressed air line should be in place	Yes	JE	4/24/17
Comments:			

JE 4/24/17

Reviewed By: _____ **Date:** 4-24-17

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	JE	4/24/17
Infeed	The start button on the control screen starts the process of feeding film through the machine	Yes	JE	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	JE	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	JE	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	JE	4/24/17
Sealer	Verify that the sealing station seals the filled pouch when it indexes into the seal station.	Yes	JE	4/24/17
Comments:				

JE 4/24/17

Reviewed By: _____ **Date:** 4-24-17

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 1	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	[illegible]	4/24/17
2	Yes	Yes	Yes	No	[illegible]	4/24/17
3	Yes	Yes	Yes	No	[illegible]	4/24/17
4	Yes	Yes	Yes	No	[illegible]	4/24/17
5	Yes	Yes	Yes	No	[illegible]	4/24/17
6	Yes	Yes	Yes	No	[illegible]	4/24/17
7	Yes	Yes	Yes	No	[illegible]	4/24/17
8	Yes	Yes	Yes	No	[illegible]	4/24/17
9	Yes	Yes	Yes	No	[illegible]	4/24/17
10	Yes	Yes	Yes	No	[illegible]	4/24/17
11	Yes	Yes	Yes	No	[illegible]	4/24/17
12	Yes	Yes	Yes	No	[illegible]	4/24/17
13	Yes	Yes	Yes	No	[illegible]	4/24/17
14	Yes	Yes	Yes	No	[illegible]	4/24/17
15	Yes	Yes	Yes	No	[illegible]	4/24/17
16	Yes	Yes	Yes	No	[illegible]	4/24/17
17	Yes	Yes	Yes	No	[illegible]	4/24/17
18	Yes	Yes	Yes	No	[illegible]	4/24/17
19	Yes	Yes	Yes	No	[illegible]	4/24/17
20	Yes	Yes	Yes	No	[illegible]	4/24/17
21	Yes	Yes	Yes	No	[illegible]	4/24/17
22	Yes	Yes	Yes	No	[illegible]	4/24/17
23	Yes	Yes	Yes	No	[illegible]	4/24/17
24	Yes	Yes	Yes	No	[illegible]	4/24/17
25	Yes	Yes	Yes	No	[illegible]	4/24/17
Comments:						

[illegible] 4/24/17

Reviewed By: [illegible] **Date:** 4-24-17

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 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	JE	4/24/17
2	Yes	Yes	Yes	No	JE	4/24/17
3	Yes	Yes	Yes	No	JE	4/24/17
4	Yes	Yes	Yes	No	JE	4/24/17
5	Yes	Yes	Yes	No	JE	4/24/17
6	Yes	Yes	Yes	No	JE	4/24/17
7	Yes	Yes	Yes	No	JE	4/24/17
8	Yes	Yes	Yes	No	JE	4/24/17
9	Yes	Yes	Yes	No	JE	4/24/17
10	Yes	Yes	Yes	No	JE	4/24/17
11	Yes	Yes	Yes	No	JE	4/24/17
12	Yes	Yes	Yes	No	JE	4/24/17
13	Yes	Yes	Yes	No	JE	4/24/17
14	Yes	Yes	Yes	No	JE	4/24/17
15	Yes	Yes	Yes	No	JE	4/24/17
16	Yes	Yes	Yes	No	JE	4/24/17
17	Yes	Yes	Yes	No	JE	4/24/17
18	Yes	Yes	Yes	No	JE	4/24/17
19	Yes	Yes	Yes	No	JE	4/24/17
20	Yes	Yes	Yes	No	JE	4/24/17
21	Yes	Yes	Yes	No	JE	4/24/17
22	Yes	Yes	Yes	No	JE	4/24/17
23	Yes	Yes	Yes	No	JE	4/24/17
24	Yes	Yes	Yes	No	JE	4/24/17
25	Yes	Yes	Yes	No	JE	4/24/17
Comments:						

JE 4/24/17

Reviewed By: _____ **Date:** 4-24-17

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 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	Yes	Yes	Yes	No	JR	4/24/17
2	Yes	Yes	Yes	No	JR	4/24/17
3	Yes	Yes	Yes	No	JR	4/24/17
4	Yes	Yes	Yes	No	JR	4/24/17
5	Yes	Yes	Yes	No	JR	4/24/17
6	Yes	Yes	Yes	No	JR	4/24/17
7	Yes	Yes	Yes	No	JR	4/24/17
8	Yes	Yes	Yes	No	JR	4/24/17
9	Yes	Yes	Yes	No	JR	4/24/17
10	Yes	Yes	Yes	No	JR	4/24/17
11	Yes	Yes	Yes	No	JR	4/24/17
12	Yes	Yes	Yes	No	JR	4/24/17
13	Yes	Yes	Yes	No	JR	4/24/17
14	Yes	Yes	Yes	No	JR	4/24/17
15	Yes	Yes	Yes	No	JR	4/24/17
16	Yes	Yes	Yes	No	JR	4/24/17
17	Yes	Yes	Yes	No	JR	4/24/17
18	Yes	Yes	Yes	No	JR	4/24/17
19	Yes	Yes	Yes	No	JR	4/24/17
20	Yes	Yes	Yes	No	JR	4/24/17
21	Yes	Yes	Yes	No	JR	4/24/17
22	Yes	Yes	Yes	No	JR	4/24/17
23	Yes	Yes	Yes	No	JR	4/24/17
24	Yes	Yes	Yes	No	JR	4/24/17
25	Yes	Yes	Yes	No	JR	4/24/17
Comments:						

JR 4/24/17

Reviewed By: _____ **Date:** 4-24-17

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 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	JR	4/24/17
2	Yes	Yes	Yes	No	JR	4/24/17
3	Yes	Yes	Yes	No	JR	4/24/17
4	Yes	Yes	Yes	No	JR	4/24/17
5	Yes	Yes	Yes	No	JR	4/24/17
6	Yes	Yes	Yes	No	JR	4/24/17
7	Yes	Yes	Yes	No	JR	4/24/17
8	Yes	Yes	Yes	No	JR	4/24/17
9	Yes	Yes	Yes	No	JR	4/24/17
10	Yes	Yes	Yes	No	JR	4/24/17
11	Yes	Yes	Yes	No	JR	4/24/17
12	Yes	Yes	Yes	No	JR	4/24/17
13	Yes	Yes	Yes	No	JR	4/24/17
14	Yes	Yes	Yes	No	JR	4/24/17
15	Yes	Yes	Yes	No	JR	4/24/17
16	Yes	Yes	Yes	No	JR	4/24/17
17	Yes	Yes	Yes	No	JR	4/24/17
18	Yes	Yes	Yes	No	JR	4/24/17
19	Yes	Yes	Yes	No	JR	4/24/17
20	Yes	Yes	Yes	No	JR	4/24/17
21	Yes	Yes	Yes	No	JR	4/24/17
22	Yes	Yes	Yes	No	JR	4/24/17
23	Yes	Yes	Yes	No	JR	4/24/17
24	Yes	Yes	Yes	No	JR	4/24/17
25	Yes	Yes	Yes	No	JR	4/24/17
Comments:						

JR 4/24/17

Reviewed By: _____ **Date:** 4-24-17

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	1 of 4
Sample #	Is the Zipper inserted? (Yes/No)	Is the Zipper in correct location? (Yes/No)	Verified By	Date
1	Yes	Yes	JE	4/24/17
2	Yes	Yes	JE	4/24/17
3	Yes	Yes	JE	4/24/17
4	Yes	Yes	JE	4/24/17
5	Yes	Yes	JE	4/24/17
6	Yes	Yes	JE	4/24/17
7	Yes	Yes	JE	4/24/17
8	Yes	Yes	JE	4/24/17
9	Yes	Yes	JE	4/24/17
10	Yes	Yes	JE	4/24/17
11	Yes	Yes	JE	4/24/17
12	Yes	Yes	JE	4/24/17
13	Yes	Yes	JE	4/24/17
14	Yes	Yes	JE	4/24/17
15	Yes	Yes	JE	4/24/17
16	Yes	Yes	JE	4/24/17
17	Yes	Yes	JE	4/24/17
18	Yes	Yes	JE	4/24/17
19	Yes	Yes	JE	4/24/17
20	Yes	Yes	JE	4/24/17
21	Yes	Yes	JE	4/24/17
22	Yes	Yes	JE	4/24/17
23	Yes	Yes	JE	4/24/17
24	Yes	Yes	JE	4/24/17
25	Yes	Yes	JE	4/24/17
Comments:				

JE 4/24/17

Reviewed By: _____ Date: 4-24-17

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	JR	4/24/17
2	Yes	Yes	JR	4/24/17
3	Yes	Yes	JR	4/24/17
4	Yes	Yes	JR	4/24/17
5	Yes	Yes	JR	4/24/17
6	Yes	Yes	JR	4/24/17
7	Yes	Yes	JR	4/24/17
8	Yes	Yes	JR	4/24/17
9	Yes	Yes	JR	4/24/17
10	Yes	Yes	JR	4/24/17
11	Yes	Yes	JR	4/24/17
12	Yes	Yes	JR	4/24/17
13	Yes	Yes	JR	4/24/17
14	Yes	Yes	JR	4/24/17
15	Yes	Yes	JR	4/24/17
16	Yes	Yes	JR	4/24/17
17	Yes	Yes	JR	4/24/17
18	Yes	Yes	JR	4/24/17
19	Yes	Yes	JR	4/24/17
20	Yes	Yes	JR	4/24/17
21	Yes	Yes	JR	4/24/17
22	Yes	Yes	JR	4/24/17
23	Yes	Yes	JR	4/24/17
24	Yes	Yes	JR	4/24/17
25	Yes	Yes	JR	4/24/17
Comments:				

JR 4/24/17

Reviewed By: _____ Date: 4-24-17

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	3 of 4
Sample #	Is the Zipper inserted? (Yes/No)	Is the Zipper in correct location? (Yes/No)	Verified By	Date
1	Yes	Yes	JR	4/24/17
2	Yes	Yes	JR	4/24/17
3	Yes	Yes	JR	4/24/17
4	Yes	Yes	JR	4/24/17
5	Yes	Yes	JR	4/24/17
6	Yes	Yes	JR	4/24/17
7	Yes	Yes	JR	4/24/17
8	Yes	Yes	JR	4/24/17
9	Yes	Yes	JR	4/24/17
10	Yes	Yes	JR	4/24/17
11	Yes	Yes	JR	4/24/17
12	Yes	Yes	JR	4/24/17
13	Yes	Yes	JR	4/24/17
14	Yes	Yes	JR	4/24/17
15	Yes	Yes	JR	4/24/17
16	Yes	Yes	JR	4/24/17
17	Yes	Yes	JR	4/24/17
18	Yes	Yes	JR	4/24/17
19	Yes	Yes	JR	4/24/17
20	Yes	Yes	JR	4/24/17
21	Yes	Yes	JR	4/24/17
22	Yes	Yes	JR	4/24/17
23	Yes	Yes	JR	4/24/17
24	Yes	Yes	JR	4/24/17
25	Yes	Yes	JR	4/24/17
Comments:				

JR 4/24/17

Reviewed By: _____ Date: 4-24-17

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	4 of 4
Sample #	Is the Zipper inserted? (Yes/No)	Is the Zipper in correct location? (Yes/No)	Verified By	Date
1	Yes	Yes	JR	4/24/17
2	Yes	Yes	JR	4/24/17
3	Yes	Yes	JR	4/24/17
4	Yes	Yes	JR	4/24/17
5	Yes	Yes	JR	4/24/17
6	Yes	Yes	JR	4/24/17
7	Yes	Yes	JR	4/24/17
8	Yes	Yes	JR	4/24/17
9	Yes	Yes	JR	4/24/17
10	Yes	Yes	JR	4/24/17
11	Yes	Yes	JR	4/24/17
12	Yes	Yes	JR	4/24/17
13	Yes	Yes	JR	4/24/17
14	Yes	Yes	JR	4/24/17
15	Yes	Yes	JR	4/24/17
16	Yes	Yes	JR	4/24/17
17	Yes	Yes	JR	4/24/17
18	Yes	Yes	JR	4/24/17
19	Yes	Yes	JR	4/24/17
20	Yes	Yes	JR	4/24/17
21	Yes	Yes	JR	4/24/17
22	Yes	Yes	JR	4/24/17
23	Yes	Yes	JR	4/24/17
24	Yes	Yes	JR	4/24/17
25	Yes	Yes	JR	4/24/17
Comments:				

JR 4/24/17

Reviewed By: _____ Date: 4-24-17

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

[illegible] 4/24/17

Reviewed By: [signature] Date: 4-24-17

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

TE 4/24/17

Reviewed By: [signature] Date: 4-24-17

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 Date Imprinting			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	JE	4/24/17	
2	Yes	Yes	JE	4/24/17	
3	Yes	Yes	JE	4/24/17	
4	Yes	Yes	JE	4/24/17	
5	Yes	Yes	JE	4/24/17	
6	Yes	Yes	JE	4/24/17	
7	Yes	Yes	JE	4/24/17	
8	Yes	Yes	JE	4/24/17	
9	Yes	Yes	JE	4/24/17	
10	Yes	Yes	JE	4/24/17	
11	Yes	Yes	JE	4/24/17	
12	Yes	Yes	JE	4/24/17	
13	Yes	Yes	JE	4/24/17	
14	Yes	Yes	JE	4/24/17	
15	Yes	Yes	JE	4/24/17	
16	Yes	Yes	JE	4/24/17	
17	Yes	Yes	JE	4/24/17	
18	Yes	Yes	JE	4/24/17	
19	Yes	Yes	JE	4/24/17	
20	Yes	Yes	JE	4/24/17	
21	Yes	Yes	JE	4/24/17	
22	Yes	Yes	JE	4/24/17	
23	Yes	Yes	JE	4/24/17	
24	Yes	Yes	JE	4/24/17	
25	Yes	Yes	JE	4/24/17	
Comments:					

JE 4/24/17

Reviewed By: _____ **Date:** 4-24-17

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 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	JH	4/24/17
2	Yes	Yes	JH	4/24/17
3	Yes	Yes	JH	4/24/17
4	Yes	Yes	JH	4/24/17
5	Yes	Yes	JH	4/24/17
6	Yes	Yes	JH	4/24/17
7	Yes	Yes	JH	4/24/17
8	Yes	Yes	JH	4/24/17
9	Yes	Yes	JH	4/24/17
10	Yes	Yes	JH	4/24/17
11	Yes	Yes	JH	4/24/17
12	Yes	Yes	JH	4/24/17
13	Yes	Yes	JH	4/24/17
14	Yes	Yes	JH	4/24/17
15	Yes	Yes	JH	4/24/17
16	Yes	Yes	JH	4/24/17
17	Yes	Yes	JH	4/24/17
18	Yes	Yes	JH	4/24/17
19	Yes	Yes	JH	4/24/17
20	Yes	Yes	JH	4/24/17
21	Yes	Yes	JH	4/24/17
22	Yes	Yes	JH	4/24/17
23	Yes	Yes	JH	4/24/17
24	Yes	Yes	JH	4/24/17
25	Yes	Yes	JH	4/24/17
Comments:				

JH 4/24/17

Reviewed By: _____ Date: 4-24-17

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

JE 4/24/17

Reviewed By: _____ **Date:** 4-24-17

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	2	of 4
Sample #	**Actual Weight (Yes/No)**	**Acceptable (Yes/No)**	**Verified By**	**Date**	
1	8.03	Yes	JR	4/24/17	
2	8.07	Yes	JR	4/24/17	
3	8.04	Yes	JR	4/24/17	
4	8.04	Yes	JR	4/24/17	
5	8.09	Yes	JR	4/24/17	
6	8.06	Yes	JR	4/24/17	
7	8.08	Yes	JR	4/24/17	
8	8.01	Yes	JR	4/24/17	
9	8.08	Yes	JR	4/24/17	
10	8.07	Yes	JR	4/24/17	
11	8.06	Yes	JR	4/24/17	
12	8.08	Yes	JR	4/24/17	
13	8.07	Yes	JR	4/24/17	
14	8.03	Yes	JR	4/24/17	
15	8.06	Yes	JR	4/24/17	
16	8.05	Yes	JR	4/24/17	
17	8.02	Yes	JR	4/24/17	
18	8.01	Yes	JR	4/24/17	
19	8.05	Yes	JR	4/24/17	
20	8.04	Yes	JR	4/24/17	
21	8.07	Yes	JR	4/24/17	
22	8.05	Yes	JR	4/24/17	
23	8.03	Yes	JR	4/24/17	
24	8.05	Yes	JR	4/24/17	
25	8.05	Yes	JR	4/24/17	
Comments:					

JR 4/24/17

Reviewed By: _____ **Date:** 4-24-17

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

JR 4/24/17

Reviewed By: [signature] **Date:** 4-24-17

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	Yes	[signature]	4/24/17
2	8.04	Yes	[signature]	4/24/17
3	8.02	Yes	[signature]	4/24/17
4	8.03	Yes	[signature]	4/24/17
5	8.05	Yes	[signature]	4/24/17
6	8.07	Yes	[signature]	4/24/17
7	8.02	Yes	[signature]	4/24/17
8	8.03	Yes	[signature]	4/24/17
9	8.04	Yes	[signature]	4/24/17
10	8.09	Yes	[signature]	4/24/17
11	8.07	Yes	[signature]	4/24/17
12	8.03	Yes	[signature]	4/24/17
13	8.08	Yes	[signature]	4/24/17
14	8.09	Yes	[signature]	4/24/17
15	8.07	Yes	[signature]	4/24/17
16	8.01	Yes	[signature]	4/24/17
17	8.03	Yes	[signature]	4/24/17
18	8.08	Yes	[signature]	4/24/17
19	8.03	Yes	[signature]	4/24/17
20	8.03	Yes	[signature]	4/24/17
21	8.05	Yes	[signature]	4/24/17
22	8.04	Yes	[signature]	4/24/17
23	8.06	Yes	[signature]	4/24/17
24	8.05	Yes	[signature]	4/24/17
25	8.03	Yes	[signature]	4/24/17
Comments:				

[signature] 4/24/17

Reviewed By: [signature] Date: 4-24-17

CALIBRATION VERIFICATION

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

Reviewed By: _____ **Date:** 4-24-17

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:			

Not used

JE 4/24/17

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:

NOT USED

4/24/17

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
Thomas Evans	Engineering / Maintenance	Thomas Evans	TE	4/24/17
Robert Eric Dennis	Quality Associate II	Robert Eric Dennis	RED	4-24-17