Approvals

Signing below indicates agreement that the execution of the Installation, Operational, and Performance Qualification Protocol for Auto Poucher #1, Leepack PSG Lee RP-84TZ 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		7/10/13
Robert Willis	Maintenance		7/11/13
Monte Plott	Production		7/11/13
Matt Haynes	Operations		7/11/13
Deborah Durbin	Quality		7/11/13

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

TABLE OF CONTENTS		Page #

I. PURPOSE:

The purpose of the protocol is to certify with documented evidence that the Auto Poucher #1 (Leepack PSG Lee RP-84TZ Serial #P-231), 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 #1 located at Giles Chemical Repackaging Unit, 396 Smathers Street, Waynesville, NC were all executed and all acceptance criteria were met.

II. SUMMARY

This Auto Poucher #1 (Leepack PSG Lee RP-84TZ Serial #P-231) was manufactured by Leepack, Inc and purchased new from PPi Technologies, Inc in Sarasota, FL. PPi had the machine manufactured in South Korea. It was installed at Giles in 2004. The machine is used to fill and seal pre-made plastic pouches, typically in 3 and 4 pound sizes.

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 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 #1 securely seals the pouch.

Fill Weights: Verification that Auto Poucher #1 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 Auto Poucher #1 (Leepack PSG Lee RP-84TZ Serial #P-231) is installed, operating, and performing as expected. Auto Poucher #1 (Leepack PSG Lee RP-84TZ Serial #P-231) is considered validated.

IV. RECOMMENDATIONS

1. It is recommended that Auto Poucher #1 (Leepack PSG Lee RP-84TZ Serial #P-231), 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:

E13-VAL-RIQ-301, Auto Poucher 1 IQ/OQ/PQ Protocol, rev 0, 6/11/2013

Appendix I: INSTALLATION QUALIFICATION

A. Installation Qualification

01. Location

a. Verify that Auto Poucher #1 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 #1 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
220 V for Machine Minimum	231
220V for Scale Minimum	231
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 #1 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 pouches onto the carousel	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
Dump Scale	Verify that when a pouch is presented by the carousel to the fill station that the filler dumps a charge into the properly presented pouch.	YES

Appendix III: PERFORMANCE QUALIFICATION

A. Firmly Sealed: Verify That the Auto Poucher #1 firmly seals the pouch with no burn and no salt leakage. Run the Auto Poucher #1 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 top scorched? (Yes/No)	Does the Seal Leak? (Yes/No)
1	YES	NO	NO
2	YES	NO	NO
3	YES	NO	NO
4	YES	NO	NO
5	YES	NO	NO
6	YES	NO	NO
7	YES	NO	NO
8	YES	NO	NO
9	YES	NO	NO
10	YES	NO	NO
11	YES	NO	NO
12	YES	NO	NO
13	YES	NO	NO
14	YES	NO	NO
15	YES	NO	NO
16	YES	NO	NO
17	YES	NO	NO
18	YES	NO	NO
19	YES	NO	NO
20	YES	NO	NO
21	YES	NO	NO
22	YES	NO	NO
23	YES	NO	NO
24	YES	NO	NO
25	YES	NO	NO

APPENDIX III TABLE I CONTINUED

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

APPENDIX III TABLE I CONTINUED

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

APPENDIX III TABLE I CONTINUED

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

PERFORMANCE QUALIFICATION (Continued)

B. Date Code Imprinting: Verify that the date code is imprinted properly and accurately.
Run the Auto Poucher #1 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)

C. Fill Weights: Verify that the fill weights are within the accepted range of 3.00+ pounds.
Run the Auto Poucher #1 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	3.10	YES
2	3.14	YES
3	3.11	YES
4	3.16	YES
5	3.14	YES
6	3.11	YES
7	3.11	YES
8	3.17	YES
9	3.14	YES
10	3.16	YES
11	3.14	YES
12	3.11	YES
13	3.13	YES
14	3.16	YES
15	3.14	YES
16	3.14	YES
17	3.15	YES
18	3.12	YES
19	3.15	YES
20	3.15	YES
21	3.13	YES
22	3.17	YES
23	3.11	YES
24	3.14	YES
25	3.16	YES

APPENDIX III TABLE III CONTINUED -

Sample #	Actual Weight	Acceptable (Yes/No)
26	3.16	YES
27	3.12	YES
28	3.15	YES
29	3.15	YES
30	3.11	YES
31	3.14	YES
32	3.12	YES
33	3.17	YES
34	3.14	YES
35	3.17	YES
36	3.12	YES
37	3.15	YES
38	3.16	YES
39	3.11	YES
40	3.17	YES
41	3.17	YES
42	3.16	YES
43	3.11	YES
44	3.12	YES
45	3.12	YES
46	3.17	YES
47	3.14	YES
48	3.12	YES
49	3.14	YES
50	3.13	YES

APPENDIX III TABLE III CONTINUED -

Sample #	Actual Weight	Acceptable (Yes/No)
51	3.17	YES
52	3.13	YES
53	3.17	YES
54	3.13	YES
55	3.14	YES
56	3.19	YES
57	3.11	YES
58	3.15	YES
59	3.13	YES
60	3.15	YES
61	3.13	YES
62	3.18	YES
63	3.11	YES
64	3.16	YES
65	3.15	YES
66	3.16	YES
67	3.15	YES
68	3.11	YES
69	3.17	YES
70	3.11	YES
71	3.13	YES
72	3.15	YES
73	3.17	YES
74	3.12	YES
75	3.17	YES

APPENDIX III TABLE III CONTINUED -

Sample #	Actual Weight	Acceptable (Yes/No)
76	3.17	YES
77	3.19	YES
78	3.14	YES
79	3.13	YES
80	3.17	YES
81	3.13	YES
82	3.05	YES
83	3.13	YES
84	3.17	YES
85	3.11	YES
86	3.12	YES
87	3.16	YES
88	3.13	YES
89	3.13	YES
90	3.17	YES
91	3.16	YES
92	3.13	YES
93	3.10	YES
94	3.16	YES
95	3.12	YES
96	3.13	YES
97	3.12	YES
98	3.15	YES
99	3.13	YES
100	3.15	YES

Approvals

Signing below indicates agreement that the protocol is ready for execution of the Installation, Operational, and Performance Qualification for Auto Poucher #1, Leepack PSG Lee RP-84TZ located at 396 Smathers Street at the Repackaging facility.

Project Team Member	Functional Area	Signature	Date
Patrick Owen	Engineering		6/11/2013
Robert Willis	Maintenance		6/11/2013
Monte Plott	Production		6/11/2013
Matt Haynes	Operations		6/11/13
Deborah Durbin	Quality		6/11/13

A final summary report that consists of results and conclusions based on the data collected after protocol execution will be written and approved. The executed protocol will be attached behind the report.

TABLE OF CONTENTS		Page #
APPROVAL PAGE		1
TABLE OF CONTENTS		2
I.	PURPOSE	3
II.	BACKGROUND	3
III.	OVERVIEW	3
IV.	SYSTEM DESCRIPTION	3
V.	SCOPE	3
VI.	ROLES AND RESPONSIBILITIES	3-4
VII.	TEST PROGRAM	4-5
A	INSTALLATION QUALIFICATION	4
B	OPERATIONAL QUALIFICATION	5
C	PERFORMANCE QUALIFICATION	5
VIII.	CALIBRATION	6
IX.	REFERENCE MATERIAL	6
ATTACHMENT I:	INSTALLATION QUALIFICATION	7
ATTACHMENT II:	OPERATIONAL QUALIFICATION	8
ATTACHMENT III:	PERFORMANCE QUALIFICATION	9-11
ATTACHMENT IV	CALIBRATION DATA SHEET	12
ATTACHMENT V:	PROTOCOL DEVIATION REPORT LOG	13
ATTACHMENT VI:	PROTOCOL DEVIATION REPORT	14
ATTACHMENT VII	SIGNATURE IDENTIFICATION LOG SHEET	15

I. PURPOSE:

The purpose of this protocol is to certify with documented evidence that the Auto Poucher #1 (Leepack PSG Lee RP-84TZ Serial #P-231), 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 #1 located at Giles Chemical Repackaging Unit, 396 Smathers Street, Waynesville, NC.

II. BACKGROUND:

This Epsom Salt Auto Poucher #1 (serial #P-231) was manufactured by Leepack and purchased used from PPi Technologies, Inc. in Sarasota, FL. PPi had the machine manufactured in South Korea and it was installed at Giles in 2004. The machine is used to fill and seal pre-made plastic pouches, typically in 3 and 4 pound sizes.

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 the Epsom Auto Poucher #1 securely seals the pouch.

Fill Weights: Verify that Auto Poucher #1 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 #1 will open, fill, and top seal plastic pouches with Epsom Salt. It is a 1 line system, opening filling, and sealing 1 pouch at a time.

B. Description of Operation

01. The empty pouches are fed into the machine by a vacuum cup system. The feeder system presents the pouches to a set of gripper arms. There are 8 sets of gripper arms mounted on a carousel. The carousel rotates the pouch through each station of the machine with intermittent motion.

02. The pouch is fed to the gripper arms, then rotates to a date stamp sation where the date code is applied. Then the pouch rotates to a zipper opening station. There, mechanical flaps open the pouch for filling. The next station is the pouch detect, air blow station. A vacuum sensor detects if suction cups are successful in opening the pouch, and air is injected into the open pouch in anticipation of filling. The next station is for filling. A 4 head scale dumps a pre-measured dose of salt into the pouch.

03. The filled pouch then indexes to a settling station and a mechanical settler gently taps the bottom of the filled pouch to settle the contents. The pouch then indexes to the sealing station, where to top of the pouch is sealed. Finally the pouch indexes to the drop station where the gripper arms release it onto a discharge conveyor.

04. From the discharge conveyor, the pouches are dropped onto a packing conveyor. Finally, the pouches are then manually packed into case packaging.

V. SCOPE

The Installation Operational Performance Qualification protocol is intended to certify with documented evidence that Auto Poucher #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 Auto Poucher #1 is installed as indicated by Leepack.

Equipment/Materials

Auto Poucher #1, PSG Lee RP-84TZ (SN P-231)

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

Procedure

Perform each listed below for Auto Poucher #1.

- 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 #1 operates as indicated by Leepack. The controls will be operated to test the ability of Auto Poucher #1 to provide adequate control for starting/stopping, pouch feed, and emergency stop.

Equipment/Materials

Auto Poucher #1, PSG Lee RP-84TZ (SN P-231)

Procedure

Test each operation of Auto Poucher #1

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 #1 performs the function required by Giles Chemical. The final product will be tested to verify:

- That Auto Poucher #1 firmly seals pouch.
- That the lot code and expiration date numbers are printed properly and accurately.
- That the fill weights are within the accepted range (3.0+ pounds for 3 pound pouches and 4.0+ pounds for 4 pound pouches).

Equipment/Materials

Auto Poucher #1, PSG Lee RP-84TZ (SN P-231)

Empty Pouch(es) (for tare)

Scale

Procedure

Run Auto Poucher #1 on 3 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 #1 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 4 pound pouches.

Acceptance Criteria

Auto Poucher #1 firmly seals the carton on both ends.

Auto Poucher #1 correctly imprints the lot code and expiration date.

That the fill weights are within the accepted range of 3.00+ pounds for 3 pound pouches and 4.00+ pounds for 4 pound pouches.

VIII. CALIBRATION

Verify that all instrumentation that requires calibration is calibrated.

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

IX. REFERENCE:

Leepack Operation Manual

AUTO POUCHER #1: INSTALLATION QUALIFICATION

A. Installation Qualification

01. Location

a. Verify that Auto Poucher #1 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	PGS	6/12/13
The machine must be located in an area that is adequately ventilated	YES	PGS	6/12/13
Comments:			

PGS 6/12/13

02. Level

a. It is important to make sure that the Auto Poucher #1 is level.

LEVEL			
Is the unit level? (Yes/No)	**Acceptable (Yes/No)**	**Verified By**	**Date**
YES	YES	PGS	6/12/13
Comments:			

PGS 6/12/13

03. Utilities

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

UTILIES			
Electrical			
Specified	**Actual**	**Verified By**	**Date**
220 V for Machine	231V	PGS	6/12/13
220 V for Scale	231V	PGS	6/12/13
60 Hz	60Hz	PGS	6/12/13
Air			
The machine requires compressed air.			
A compressed air line should be in place	YES	PGS	6/12/13
Comments:	220V is minimum - 231V is acceptable		

PGS 6/12/13

Reviewed By: Patrick Owen **Date:** 7-8-13

AUTO POUCHER #1: OPERATIONAL QUALIFICATION

B. Operation Qualification

01. Controls/Indicators Verification – to document that Auto Poucher #1 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	PEV	6/12/13
Infeed	The infeed button on the control screen starts the process of feeding pouches onto the carousel	YES	PEV	6/12/13
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	PEV	6/12/13
Date Coder	Verify that the date coder stamps a date code on the pouch as it indexes to the date code station.	YES	PEV	6/12/13
Dump Scale	Verify that when a pouch is presented by the carousel to the fill station that the filler dumps a charge into the properly presented pouch.	YES	PEV	6/12/13
Sealer	Verify that the sealing station seals the filled pouch when it indexes into the seal station.	YES	PEV	6/12/13
Comments:				

PEV 6/12/13

Reviewed By: Brook Vaughn **Date:** 7-8-13

AUTO POUCHER #1: PERFORMANCE QUALIFICATION

C. Firmly Sealed: Verify That Auto Poucher #1 firmly seals the pouch.

Run Auto Poucher #2 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 top scorched? (Yes/No)	Does the seal leak? (Yes/No)	Verified By	Date
1	Y	N	N	PSV	6/27/13
2	Y	N	N		
3	Y	N	N		
4	Y	N	N		
5	Y	N	N		
6	Y	N	N		
7	Y	N	N		
8	Y	N	N		
9	Y	N	N		
10	Y	N	N		
11	Y	N	N		
12	Y	N	N	PSV	6/27/13
13	Y	N	N		
14	Y	N	N		
15	Y	N	N		
16	Y	N	N		
17	Y	N	N		
18	Y	N	N		
19	Y	N	N		
20	Y	N	N		
21	Y	N	N		
22	Y	N	N		
23	Y	N	N		
24	Y	N	N		
25	Y	N	N	PSV	6/27/13
Comments:					

PSV 6/27/13

Reviewed By: Brian Vaughn **Date:** 7-8-13

AUTO POUCHER #1: PERFORMANCE QUALIFICATION

C. Firmly Sealed: Verify That Auto Poucher #1 firmly seals the pouch.

Run Auto Poucher #2 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 top scorched? (Yes/No)	Does the seal leak? (Yes/No)	Verified By	Date
1	Y	N	N	DPO	6/27/13
2	Y	N	N		
3	Y	N	N		
4	Y	N	N		
5	Y	N	N		
6	Y	N	N		
7	Y	N	N		
8	Y	N	N		
9	Y	N	N		
10	Y	N	N		
11	Y	N	N		
12	Y	N	N		
13	Y	N	N	DPO	6/27/13
14	Y	N	N		
15	Y	N	N		
16	Y	N	N		
17	Y	N	N		
18	Y	N	N		
19	Y	N	N		
20	Y	N	N		
21	Y	N	N		
22	Y	N	N		
23	Y	N	N		
24	Y	N	N		
25	Y	N		DPO	6/27/13
Comments:					

DPO 6/27/13

Reviewed By: Brook Vaughn **Date:** 7-8-13

AUTO POUCHER #1: PERFORMANCE QUALIFICATION

C. Firmly Sealed: Verify That Auto Poucher #1 firmly seals the pouch.

Run Auto Poucher #2 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 top scorched? (Yes/No)	Does the seal leak? (Yes/No)	Verified By	Date
1	Y	N	N	PSV	6/27/13
2	Y	N	N		
3	Y	N	N		
4	Y	N	N		
5	Y	N	N		
6	Y	N	N		
7	Y	N	N		
8	Y	N	N		
9	Y	N	N		
10	Y	N	N		
11	Y	N	N		
12	Y	N	N	PSV	6/27/13
13	Y	N	N		
14	Y	N	N		
15	Y	N	N		
16	Y	N	N		
17	Y	N	N		
18	Y	N	N		
19	Y	N	N		
20	Y	N	N		
21	Y	N	N		
22	Y	N	N		
23	Y	N	N		
24	Y	N	N		
25	Y	N	N	PSV	6/27/13
Comments:					

PSV 6/27/13

Reviewed By: Brook Vaughn Date: 7-8-13

AUTO POUCHER #1: PERFORMANCE QUALIFICATION

C. Firmly Sealed: Verify That Auto Poucher #1 firmly seals the pouch.

Run Auto Poucher #2 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 top scorched? (Yes/No)	Does the seal leak? (Yes/No)	Verified By	Date
1	Y	N	N	PSV	6/27/13
2	Y	N	N	|	|
3	Y	N	N	|	|
4	Y	N	N	|	|
5	Y	N	N	|	|
6	Y	N	N	|	|
7	Y	N	N	|	|
8	Y	N	N	|	|
9	Y	N	N	|	|
10	Y	N	N	|	|
11	Y	N	N	|	|
12	Y	N	N	|	|
13	Y	N	N	PSV	6/27/13
14	Y	N	N	|	|
15	Y	N	N	|	|
16	Y	N	N	|	|
17	Y	N	N	|	|
18	Y	N	N	|	|
19	Y	N	N	|	|
20	Y	N	N	|	|
21	Y	N	N	|	|
22	Y	N	N	|	|
23	Y	N	N	|	|
24	Y	N	N	|	|
25	Y	N	N	PSV	6/27/13
Comments:					PSV 6/27/13

Reviewed By: Brad Vaughn **Date:** 7-8-13

AUTO POUCHER #1: PERFORMANCE QUALIFICATION (Continued)

A. Date Code Imprinting: Verify that the date code is imprinted properly and accurately. Run the Auto Poucher #1 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	Y	Y	PSr	6/27/13
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	PSr	6/27/13
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	PSr	6/27/13
Comments:				

PSr 6/27/13

Reviewed By: Brook Vaughn Date: 7-8-13

AUTO POUCHER #1: PERFORMANCE QUALIFICATION (Continued)

A. Date Code Imprinting: Verify that the date code is imprinted properly and accurately.
Run the Auto Poucher #1 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	Y	Y	PSV	6/27/13	
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	PSV	6/27/13	
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	PSV	6/27/13	

Comments: PSV 6/27/13

Reviewed By: Brook Vaughn Date: 7-8-13

AUTO POUCHER #1: PERFORMANCE QUALIFICATION (Continued)

A. Date Code Imprinting: Verify that the date code is imprinted properly and accurately.
Run the Auto Poucher #1 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	Y	Y	PSO	6/27/13	
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	PSO	6/27/13	
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	PSO	6/27/13	
Comments:					PSO 6/27/13

Reviewed By: Brook Vaughn Date: 7-8-13

AUTO POUCHER #1: PERFORMANCE QUALIFICATION (Continued)

A. Date Code Imprinting: Verify that the date code is imprinted properly and accurately.

Run the Auto Poucher #1 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	Y	Y	PSV	6/27/13	
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	PSV	6/27/13	
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	PSV	6/27/13	
Comments:					

PSV 6/27/13

Reviewed By: Brook Vaughn Date: 7-8-13

AUTO POUCHER #1: PERFORMANCE QUALIFICATION (Continued)

A. **Fill Weights:** Verify that the fill weights are within the accepted range of 3.00+ Pounds or 4.00+ Pounds (circle one). Run the Auto Poucher #1 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	3.10	Y	PSV	6/27/13	
2	3.14	Y			
3	3.11	Y			
4	3.16	Y			
5	3.14	Y			
6	3.11	Y			
7	3.11	Y			
8	3.17	Y			
9	3.14	Y			
10	3.16	Y			
11	3.14	Y	PSV	6/27/13	
12	3.11	Y			
13	3.13	Y			
14	3.16	Y			
15	3.14	Y			
16	3.14	Y			
17	3.15	Y			
18	3.12	Y			
19	3.15	Y			
20	3.15	Y			
21	3.13	Y			
22	3.17	Y			
23	3.11	Y			
24	3.14	Y			
25	3.16	Y	PSV	6/27/13	
Comments:					

PSV 6/27/13

Reviewed By: Brook Vaughn Date: 7-8-13

AUTO POUCHER #1: PERFORMANCE QUALIFICATION (Continued)

A. Fill Weights: Verify that the fill weights are within the accepted range of 3.00+ Pounds or 4.00+ Pounds (circle one). Run the Auto Poucher #1 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	3.16	Y	PSV	6/27/13
2	3.12	Y		
3	3.15	Y		
4	3.15	Y		
5	3.11	Y		
6	3.19	Y		
7	3.12	Y		
8	3.17	Y		
9	3.14	Y		
10	3.17	Y		
11	3.12	Y	PSV	6/27/13
12	3.15	Y		
13	3.16	Y		
14	3.11	Y		
15	3.17	Y		
16	3.17	Y		
17	3.16	Y		
18	3.11	Y		
19	3.12	Y		
20	3.12	Y		
21	3.17	Y		
22	3.14	Y		
23	3.12	Y		
24	3.14	Y		
25	3.13	Y	PSV	6/27/13
Comments:				

per 6/27/13

Reviewed By: Brook Thuston Date: 7-8-13

AUTO POUCHER #1: PERFORMANCE QUALIFICATION (Continued)

A. **Fill Weights:** Verify that the fill weights are within the accepted range of 3.00+ Pounds or 4.00+ Pounds (circle one). Run the Auto Poucher #1 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	3.17	Y	PSV	6/27/13	
2	3.13	Y			
3	3.17	Y			
4	3.13	Y			
5	3.14	Y			
6	3.19	Y			
7	3.11	Y			
8	3.15	Y			
9	3.13	Y			
10	3.15	Y			
11	3.13	Y			
12	3.18	Y	PSV	6/27/13	
13	3.11	Y			
14	3.16	Y			
15	3.15	Y			
16	3.16	Y			
17	3.15	Y			
18	3.11	Y			
19	3.17	Y			
20	3.11	Y			
21	3.13	Y			
22	3.15	Y			
23	3.14	Y			
24	3.12	Y			
25	3.17	Y	PSV	6/27/13	

Comments: PSV 6/27/13

Reviewed By: Brian Vaughn Date: 7-8-13

AUTO POUCHER #1: PERFORMANCE QUALIFICATION (Continued)

A. Fill Weights: Verify that the fill weights are within the accepted range of 3.00+ Pounds or 4.00+ Pounds (circle one). Run the Auto Poucher #1 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	3.17	Y	PSr	6/27/13	
2	3.19	Y			
3	3.14	Y			
4	3.13	Y			
5	3.17	Y			
6	3.13	Y			
7	3.05	Y			
8	3.13	Y			
9	3.17	Y			
10	3.11	Y			
11	3.12	Y			
12	3.16	Y	PSr	6/27/13	
13	3.13	Y			
14	3.13	Y			
15	3.17	Y			
16	3.16	Y			
17	3.13	Y			
18	3.10	Y			
19	3.16	Y			
20	3.12	Y			
21	3.13	Y			
22	3.12	Y			
23	3.15	Y			
24	3.13	Y			
25	3.15	Y	PSr	6/27/13	
Comments:					

PSr 6/27/13

Reviewed By: Brian Vaughn Date: 7-8-13

CALIBRATION VERIFICATION

Equipment	Serial #	Calibration Date	Calibration Due Date	Verified By	Date
Scale	S6310793-502	6/13/2013	7/13/2013	PSO	6/27/13
Multimeter	10010022 1	at manufactur	N/A	PSO	6/27/13

Reviewed By: Brad Vaughn Date: 7-8-13

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:			

PEP 6/27/13

PEP 6/27/13

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: _____

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	Process Engineer		PWO	6/12/13
Brook Vaughn	Quality Assc.	Brook Vaughn	BV	7-8-13