## Approvals

Signing below indicates agreement that the protocol is ready for execution of the Installation, Operational, and Performance Qualification for Auto Poucher #5, PakSource PSG RP-6TZE-30, located at 109 Giles Place in Waynesville, NC.

| Project Team Member | Functional Area | Signature | Date |
|---|---|---|---|
| Patrick Owen | Engineering | | 2/23/16 |
| Thomas Evans | Maintenance | | 2/23/16 |
| Monte Plott | Production | | 2/23/16 |
| Matt Haynes | Operations | | 2/23/16 |
| Deborah Durbin | Quality | | 2/23/16 |

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 #5 (Serial #P-1521), 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 #5 located at Giles Chemical, 109 Giles Place, Waynesville, NC.

## II. BACKGROUND:

This Epsom Salt Auto Poucher #5 (serial # P-1521) was manufactured by Leepack and purchased used from Paksource Global, Inc. in Sarasota, FL. Paksource had the machine manufactured in South Korea and it will be installed at Giles in February 2016. The machine will be used to fill and seal pre-made plastic pouches, typically in 3 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 Auto Poucher #5 securely seals the pouch.

Fill Weights: Verify that Auto Poucher #5 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 #5 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 6 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 station 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 cup filler dumps a pre-measured charge of salt into the pouch.

03. 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 #5 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 #5 is installed as indicated by Paksource Global, LLC..

Equipment/Materials

Auto Poucher #5, PakSource Global LLC PSG RP-6TZ-30 (serial # P-1521)

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

Procedure

Perform each listed below for Auto Poucher #5.

- 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 #5 operates as indicated by Leepack. The controls will be operated to test the ability of Auto Poucher #5 to provide adequate control for starting/stopping, pouch feed, and emergency stop.

Equipment/Materials

Auto Poucher #5, PakSource Global LLC PSG RP-6TZ-30 (serial # P-1521)

Procedure

Test each operation of Auto Poucher #5

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

- That Auto Poucher #5 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).

Equipment/Materials

Auto Poucher #5, PakSource Global LLC PSG RP-6TZ-30 (serial # P-1521)

Empty Pouch(es) (for tare)

Scale

Procedure

Run Auto Poucher #5 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 #5 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.

Acceptance Criteria

Auto Poucher #5 firmly seals the carton on both ends.

Auto Poucher #5 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.

## VIII. CALIBRATION

Verify that all instrumentation that requires calibration is calibrated.

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

## IX. REFERENCE:

Paksource Global, LLC Operation Manual

## AUTO POUCHER #4: INSTALLATION QUALIFICATION

### A. Installation Qualification

#### 01. Location

a. Verify that Auto Poucher #5 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 | | | |
| The machine must be located in an area that is adequately ventilated | | | |
| **Comments:** | | | |

#### 02. Level

a. It is important to make sure that the Auto Poucher #5 is level.

| LEVEL | | | |
|---|---|---|---|
| **Is the unit level? (Yes/No)** | **Acceptable (Yes/No)** | **Verified By** | **Date** |
| | | | |
| **Comments:** | | | |

#### 03. Utilities

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

| UTILIES | | | |
|---|---|---|---|
| **Electrical** | | | |
| **Specified** | **Actual** | **Verified By** | **Date** |
| 240 V +/- 20 V for Machine | | | |
| 240 V +/- 20 V for Scale | | | |
| 60 Hz | | | |
| **Air** | | | |
| The machine requires compressed air. | | | |
| A compressed air line should be in place | | | |
| **Comments:** | | | |

**Reviewed By:** _____ **Date:** _____

## AUTO POUCHER #4: OPERATIONAL QUALIFICATION

### B. Operation Qualification

**01. Controls/Indicators Verification** – to document that Auto Poucher #5 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 | | | |
| Infeed | The infeed button on the control screen starts the process of feeding pouches onto the carousel | | | |
| 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. | | | |
| Date Coder | Verify that the date coder stamps a date code on the pouch as it indexes to the date code station. | | | |
| 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. | | | |
| Sealer | Verify that the sealing station seals the filled pouch when it indexes into the seal station. | | | |
| **Comments:** | | | | |

**Reviewed By:** _____ **Date:** _____

**AUTO POUCHER #5: PERFORMANCE QUALIFICATION**

**C. Firmly Sealed:** Verify That Auto Poucher #5 firmly seals the pouch.

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

**Reviewed By:** _____ **Date:** _____

## AUTO POUCHER #5: PERFORMANCE QUALIFICATION (Continued)

**A. Date Code Imprinting:** Verify that the date code is imprinted properly and accurately.
Run the Auto Poucher #5 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 | | of 4 |
|---|---|---|---|---|---|
| Sample # | Is the Date Code visible? (Yes/No) | Is the Date Code correct? (Yes/No) | Verified By | Date | |
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | | | |
| 4 | | | | | |
| 5 | | | | | |
| 6 | | | | | |
| 7 | | | | | |
| 8 | | | | | |
| 9 | | | | | |
| 10 | | | | | |
| 11 | | | | | |
| 12 | | | | | |
| 13 | | | | | |
| 14 | | | | | |
| 15 | | | | | |
| 16 | | | | | |
| 17 | | | | | |
| 18 | | | | | |
| 19 | | | | | |
| 20 | | | | | |
| 21 | | | | | |
| 22 | | | | | |
| 23 | | | | | |
| 24 | | | | | |
| 25 | | | | | |
| Comments: | | | | | |

**Reviewed By:** _____ **Date:** _____

## AUTO POUCHER #5: PERFORMANCE QUALIFICATION (Continued)

**A. Fill Weights:** Verify that the fill weights are within the accepted range of 3.00+ pounds.
Run the Auto Poucher #5 for 4 hours while randomly sampling 25 pouches per hour for testing, for a total sample size of 100 cartons.

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

**Reviewed By:** _____ **Date:** _____

**CALIBRATION VERIFICATION**

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

**Reviewed By:** _____ **Date:** _____

**ATTACHMENT I - PROTOCOL DEVIATION REPORT LOG**

Log each Protocol Deviation Report in the table below. Attach the PDRs to this Attachment.

| PDR # | DESCRIPTION | DATE INITIATED | DATE RESOLVED |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| **Comments:** | | | |

## 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 |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |