

**GILES CHEMICAL ~ PREMIER MAGNESIA****Validation Protocol**

Title: Hayssen Bagger IQ/OQ/PQ Final Report

Number: E16-VAL-PFR-511

Owner: Kenneth Basehore

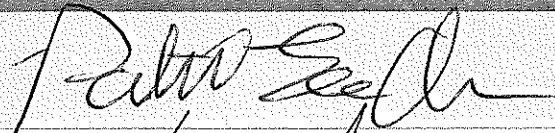


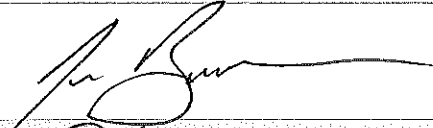
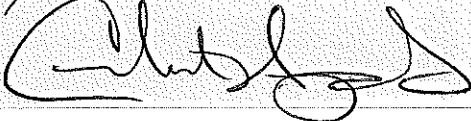

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**I. Approvals**

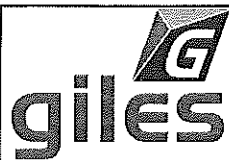
Signing below indicates agreement that the execution of the Installation, Operational and Performance Qualification Protocol (E16-VAL-PIQ-510) for the Hayssen Bagger model SV 18-27 HP (s/n U89375), located at 102 Commerce Street, is complete and the process is validated.

Project Member	Functional Area	Signature	Date
Patrick Owen	Engineering		11/16/16
Kenneth Basehore	Engineering		11/16/16
Sammy Henson	Maintenance		11/16/16
Jason Bumgarner	Production		11-16-16
Matt Haynes	Operations		11-16-16
Deborah Durbin	Quality		11-28-16

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

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## II. Purpose

The purpose of this protocol is to certify with documented evidence that the Hayssen Bagger model SV 18-27 HP (s/n U89375), 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 Hayssen Bagger model SV 18-27 HP, located at 102 Commerce Street at the Main Plant production facility.

## III. Summary

This bagger model SV 18-27 HP (s/n U89375) was manufactured by Hayssen in Duncan, SC. It was installed at Giles in July of 2016. The machine will be used to fill and seal plastic bags, typically a 50-pound size.

The following tests were performed during this qualification:

- Controls/Indicators verification – to document that the start/stop, emergency stop and feed controls work correctly.
- Lot code and expiration date verification – to document that the lot code is printed and legible on each bag.
- Sealed bag verification – to document that the bag is sealed correctly on the bottom, top and side.
- Fill weight verification – to document that the equipment fills the correct amount of Epsom Salt in each bag.

All installation, operational and performance acceptance criteria were met as displayed in the attached executed protocol.

## IV. Conclusion

The results of the completed installation, operational and performance qualification protocol show that all acceptance criteria were met for all samples. All testing results provide documented evidence that the Hayssen Bagger model SV 18-27 HP (s/n U89375) is installed, is operating and is performing as expected.

The lot tested was 4516 AFF 06. The Hayssen Bagger model SV 18-27 HP (s/n U89375) is considered validated.

## V. Recommendations

It is recommended that the Hayssen Bagger model SV 18-27 HP (s/n U89375), located at the Giles Chemical Main Plant at 102 Commerce Street, Waynesville, NC 28786 be considered validated based on meeting the acceptance criteria of the IQ/OQ/PQ protocol.

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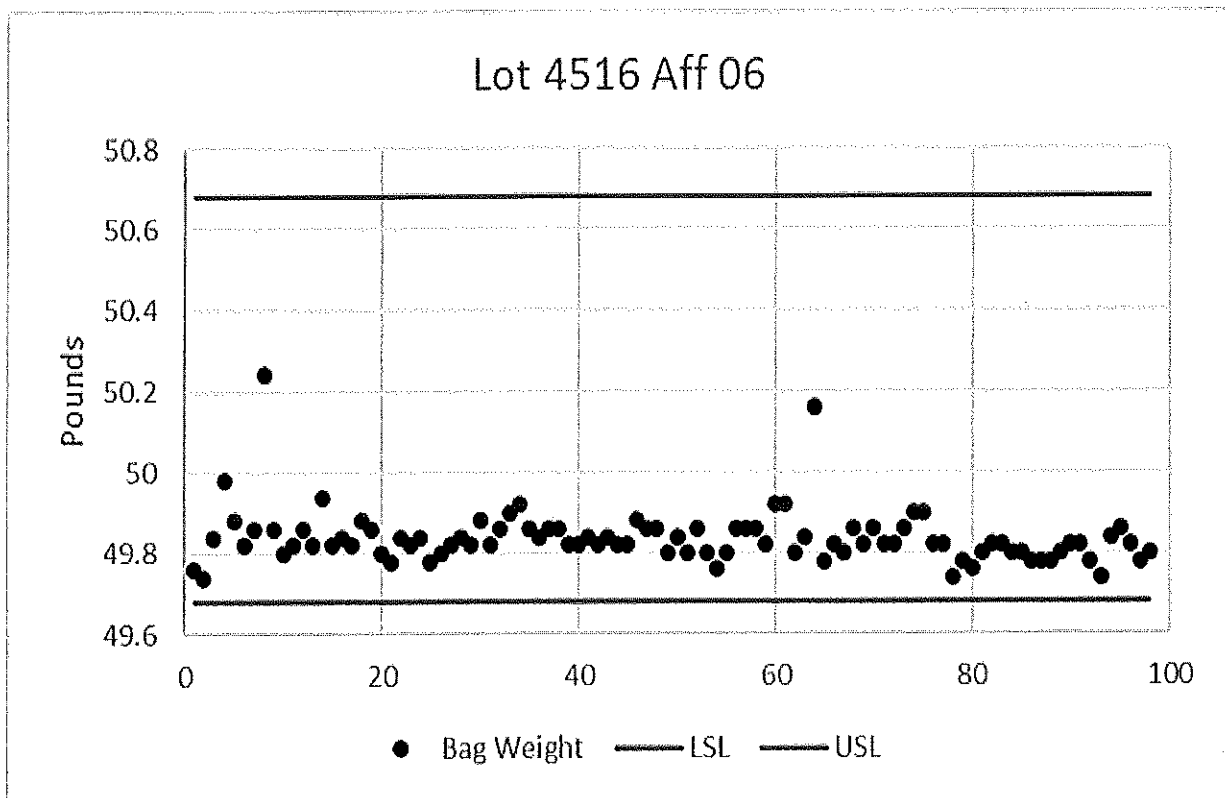
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## VI. References

E16-VAL-PIQ-510: Hayssen Bagger IQ/OQ/PQ Validation Protocol

## VII. Summary of Weight Data



Lot 4516 AFF 06. Two pallets (98 bags) were sampled and weighed. All data falls within the specified limits of 49.68 – 50.68 gross pounds.

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