Approvals

Signing below indicates agreement that the protocol is ready for execution of the Manufacturing Cleaning Validation for Giles Repackaging located at 102 Commerce Street, Waynesville, NC.

Project Team Member	Functional Area	Signature	Date
Patrick Owen	Engineering		11/7/14
Sammy Joe Henson	Maintenance		11/7/14
Jason Bumgarner	Production		11-7-14
Matt Haynes	Operations		11-7-14
Deborah Durbin	Quality		11-7-14

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 #

I. PURPOSE:

The purpose of this protocol is to certify with documented evidence that the Weekly Cleaning for Manufacturing, when followed properly, does not introduce impurities into the process.

II. BACKGROUND:

Giles only produces one product, Epsom Salt. A weekly clean up is performed, but not for product changeover. The weekly cleaning is to remove buildup in the equipment and segregate salt for traceability. The only material used for cleaning is city water.

The products that are impacted by this study are all Epsom Salt products manufactured by Giles Chemical.

III. SCOPE

This validation covers the Weekly Cleaning for Manufacturing which includes the Epsom Salt manufacturing process at 102 Commerce Street in Waynesville, NC.

IV. ROLES AND RESPONSIBILITIES

1. Engineering
   - ❖ Write and issue the protocol
   - ❖ Investigate protocol deviation reports
   - ❖ 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.
   - ❖ Source and provide clean sample bottles.
   - ❖ Test the rinse sample provided.
   - ❖ Review, approve, and store the final report.
3. Maintenance
   - ❖ Provide Access to equipment for sampling if needed.
   - ❖ Review and approve the protocol.
4. Production
   - ❖ Review and approve the protocol
   - ❖ Execute the Cleaning Procedure correctly.
   - ❖ Gather and properly label rinse samples.
   - ❖ Review and approve the final report.

V. TEST PROGRAM

A. AT MANUFACTURING

Objective: Repeat the standard Weekly Clean Day 15 times to over a 15 week period to account for variability in the cleaning process.

Equipment/Materials:

Process Equipment

City Water hoses

Procedure

1. Clean up the equipment as normal per Weekly Clean Day Log (P12-FM-100-017)
2. Quality Assurance will sample and test the product after cleaning for USP testing.
3. Repeat each week for 15 weeks.

B. AT QUALITY ASSURANCE LAB

1. Evaluate samples for USP criteria as normal. Record data.

VI. ACCEPTANCE CRITERIA

The Weekly Cleaning will be considered validated if the following criteria are all met:

1. All of the USP testing parameters pass their respective specifications per COA.

VII. CALIBRATION

Laboratory testing equipment is calibrated and in proper working order.

VIII. REFERENCE:

Weekly Clean Day Log (P12-FM-100-017)

Repack Cleaning Validation Data Sheet

Date	Week	Appearance	Cl	Heavy Metals	Ignition Loss	Iron	MgSO4	MgSO4	pH	Selenium	Mg2+	SO42-
	1											
	2											
	3											
	4											
	5											
	6											
	7											
	8											
	9											
	10											
	11											
	12											
	13											
	14											
	15											
Comments:												

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 I. 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