

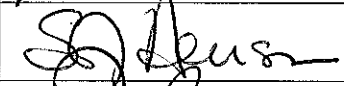

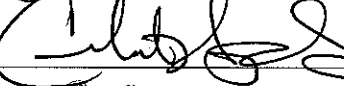
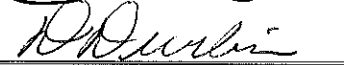
	GILES CHEMICAL ~ PREMIER MAGNESIA		
	Validation Final Report		
	Title: Manufacturing Cleaning Validation Final Report	Number: E14-VAL-PFR-006	
	Owner: Patrick Owen	Revision: 0	
	Effective Date: March 17, 2015	Page: 1 of 4	

Approvals

Signing below indicates agreement that the Weekly Cleaning Process has been validated for the Manufacturing Plant located at 102 Commerce Street, Waynesville, NC.

Project Team Member	Functional Area	Signature	Date
Patrick Owen	Engineering		3/17/15
Sammy Joe Henson	Maintenance		3/17/15
Joe Rogers	Production		3/17/15
Matt Haynes	Operations		3/17/15
Deborah Durbin	Quality		3/17/15

The executed protocol and COA data are attached behind the report.

Controlled Document

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**GILES CHEMICAL ~ PREMIER MAGNESIA****Validation Final Report**Title: Manufacturing Cleaning Validation Final
Report

Number: E14-VAL-PFR-006

Owner: Patrick Owen

Revision: 0

Effective Date: March 17, 2015

Page: 2 of 4

PREMIER
MAGNESIA, LLC**TABLE OF CONTENTS****Page #****APPROVAL PAGE****1****TABLE OF CONTENTS****2****I. PURPOSE****3****II. SUMMARY****3****III. CONCLUSION****3****IV. RECOMMENDATION****3****V. REFERENCE****3****ATTACHMENT I****VALIDATION DATA SHEET****4****ATTACHMENT****EXECUTED PROTOCOL****ATTACHMENT****COA DATA****Controlled Document**

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**GILES CHEMICAL ~ PREMIER MAGNESIA****Validation Final Report**

Title: Manufacturing Cleaning Validation Final Report

Number: E14-VAL-PFR-006

Owner: Patrick Owen

Revision: 0

Effective Date: March 17, 2015

Page: 3 of 4

**I. PURPOSE:**

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

II. SUMMARY:

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.

A normal weekly clean up was followed for 15 weeks and the USP testing data from the start-up sample were tabulated and compared to USP specifications. All samples passed all of the USP criteria.

III. CONCLUSION

These data indicate that the Weekly Cleaning at the Manufacturing Main Plant at 102 Commerce Street in Waynesville, NC has no negative effect on the quality of the final product, Epsom Salt, USP.

IV. RECOMMENDATION

It is recommended that the Weekly Cleaning process for the Manufacturing Main Plant at 102 Commerce Street in Waynesville, NC be considered to be validated.

V. REFERENCE:

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

Controlled Document

**GILES CHEMICAL ~ PREMIER MAGNESIA****Validation Final Report**

Title: Manufacturing Cleaning Validation Final Report

Number: E14-VAL-PFR-006

Owner: Patrick Owen

Revision: 0

Effective Date: March 17, 2015

Page: 4 of 4

**Appendix I - Manufacturing Cleaning Validation Data**

Date	Week	Appearance	Cl %	Heavy Metals %	Ignition Loss %	Iron ppm	MgSO4 % Hepta	MgSO4 % Anhy.	pH	Selenium %	Mg2+	SO42-	All Pass?
11/15/14	1	Clear	<0.0140	<0.001	51.23	<20.00	100.02	48.81	5.00	<0.003	Present	Present	Y
11/22/14	2	Clear	<0.0140	<0.001	51.00	<20.00	99.75	48.68	8.11	<0.003	Present	Present	Y
11/29/14	3	Clear	<0.0140	<0.001	50.84	<20.00	99.71	48.66	6.78	<0.003	Present	Present	Y
12/6/14	4	Clear	<0.0140	<0.001	51.21	<20.00	99.85	48.73	8.11	<0.003	Present	Present	Y
12/13/14	5	Clear	<0.0140	<0.001	50.96	<20.00	99.42	48.52	6.82	<0.003	Present	Present	Y
12/22/14	6	Clear	<0.0140	<0.001	50.98	<20.00	99.78	48.69	6.59	<0.003	Present	Present	Y
12/29/14	7	Clear	<0.0140	<0.001	50.32	<20.00	99.54	48.57	5.51	<0.003	Present	Present	Y
1/10/15	8	Clear	<0.0140	<0.001	50.83	<20.00	100.40	49.00	6.86	<0.003	Present	Present	Y
1/17/15	9	Clear	<0.0140	<0.001	50.81	<20.00	100.31	48.95	8.18	<0.003	Present	Present	Y
1/24/15	10	Clear	<0.0140	<0.001	50.91	<20.00	99.66	48.63	8.97	<0.003	Present	Present	Y
1/31/15	11	Clear	<0.0140	<0.001	51.15	<20.00	100.45	49.02	8.82	<0.003	Present	Present	Y
2/6/15	12	Clear	<0.0140	<0.001	50.74	<20.00	100.31	48.95	7.86	<0.003	Present	Present	Y
2/14/15	13	Clear	<0.0140	<0.001	51.28	<20.00	100.40	49.00	8.92	<0.003	Present	Present	Y
2/21/15	14	Clear	<0.0140	<0.001	51.02	<20.00	99.97	48.79	8.50	<0.003	Present	Present	Y
2/28/15	15	Clear	<0.0140	<0.001	51.01	<20.00	99.78	48.69	8.79	<0.003	Present	Present	Y

Controlled Document

Only those quality documents viewed through the Giles Chemical electronic Documentation System are officially controlled. All other copies, whether viewed through another computer program or a printed version, are not controlled and, therefore, the Quality Unit at Giles assumes no responsibility for accuracy of the document.

**GILES CHEMICAL ~ PREMIER MAGNESIA****Validation Protocol**Title: Manufacturing Cleaning Validation
Protocol

Number: E14-VAL-PIQ-005

Owner: Patrick Owen

Revision: 0

Effective Date: November 7, 2014

Page: 1 of 8

**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.

Controlled Document

Only those quality documents viewed through the Giles Chemical electronic Documentation System are officially controlled. All other copies, whether viewed through another computer program or a printed version, are not controlled and, therefore, the Quality Unit at Giles assumes no responsibility for accuracy of the document.

**GILES CHEMICAL ~ PREMIER MAGNESIA****Validation Protocol**Title: Manufacturing Cleaning Validation
Protocol

Number: E14-VAL-PIQ-005

Owner: Patrick Owen

Revision: 0

Effective Date: November 7, 2014



Page: 2 of 8

PREMIER
MAGNESIA, LLC

TABLE OF CONTENTS		Page #
APPROVAL PAGE		1
TABLE OF CONTENTS		2
I.	PURPOSE	3
II.	BACKGROUND	3
III.	SCOPE	3
IV.	ROLES AND RESPONSIBILITIES	3
V.	TEST PROGRAM	4
A	MANUFACTURING	4
B	QUALITY ASSURANCE LAB	4
VI.	ACCEPTANCE CRITERIA	4
VII.	CALIBRATION	4
VIII.	REFERENCE MATERIAL	4
ATTACHMENT	VALIDATION DATA SHEET	5
ATTACHMENT	PROTOCOL DEVIATION REPORT LOG	6
ATTACHMENT	PROTOCOL DEVIATION REPORT	7
ATTACHMENT	SIGNATURE IDENTIFICATION LOG SHEET	8

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	GILES CHEMICAL ~ PREMIER MAGNESIA		
	Validation Protocol		
	Title: Manufacturing Cleaning Validation Protocol	Number: E14-VAL-PIQ-005	
	Owner: Patrick Owen	Revision: 0	
	Effective Date: November 7, 2014	Page: 3 of 8	

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.

Controlled Document

	GILES CHEMICAL ~ PREMIER MAGNESIA		
	Validation Protocol		
	Title: Manufacturing Cleaning Validation Protocol	Number: E14-VAL-PIQ-005	
	Owner: Patrick Owen	Revision: 0	
	Effective Date: November 7, 2014	Page: 4 of 8	

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)

Controlled Document



GILES CHEMICAL ~ PREMIER MAGNESIA

Validation Protocol

Title: Manufacturing Cleaning Validation
Protocol

Number: E14-VAL-PIQ-005

Owner: Patrick Owen

Revision: 0

Effective Date: November 7, 2014

Page: 5 of 8

PREMIER
MAGNESIA, LLC

Repack Cleaning Validation Data Sheet

Date	Week	Appearance	Cl	Heavy Metals	Ignition Loss	Iron	MgSO4	MgSO4	pH	Selenium	Mg2+	SO42-
11/15/14	1	Clear	0.014	0.001	51.23	20.00	100.02	48.81%	5.00	0.003	Present	Present
11/22/14	2	Clear	0.014	0.001	51.00	20.00	99.75	48.68%	8.11	0.003	Present	Present
11/29/14	3	Clear	0.014	0.001	50.84	20.00	99.71	48.66	6.78	0.003	Present	Present
12/06/14	4	Clear	0.014	0.001	51.21	20.00	99.85	48.73	8.11	0.003	Present	Present
12/13/14	5	Clear	0.014	0.001	50.96	20.00	99.42	48.52	6.82	0.003	Present	Present
12/22/14	6	Clear	0.014	0.001	50.98	20.00	99.78	48.69	6.59	0.003	Present	Present
12/29/14	7	Clear	0.014	0.001	50.32	20.00	99.54	48.57	5.51	0.003	Present	Present
1/10/15	8	Clear	0.014	0.001	50.83	20.00	100.40	49.00	6.86	0.003	Present	Present
1/17/15	9	Clear	0.014	0.001	50.81	20.00	100.31	48.95	8.14	0.003	Present	Present
1/24/15	10	Clear	0.014	0.001	50.91	20.00	99.66	48.63	8.97	0.003	Present	Present
1/31/15	11	Clear	0.014	0.001	51.15	20.00	100.45	49.02	8.82	0.003	Present	Present
2/06/15	12	Clear	0.014	0.001	50.74	20.00	100.31	48.95	7.86	0.003	Present	Present
2/14/15	13	Clear	0.014	0.001	51.28	20.00	100.40	49.00	8.92	0.003	Present	Present
2/21/15	14	Clear	0.014	0.001	51.02	20.00	99.97	48.79	8.50	0.003	Present	Present
2/28/15	15	Clear	0.014	0.001	51.01	20.00	99.78	48.69	8.79	0.003	Present	Present

Comments:

Reviewed By:

Date:

3-2-15

P. Owen 3/2/15

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**GILES CHEMICAL ~ PREMIER MAGNESIA****Validation Protocol**Title: Manufacturing Cleaning Validation
Protocol

Number: E14-VAL-PIQ-005

Owner: Patrick Owen

Revision: 0

Effective Date: November 7, 2014

Page: 7 of 8

**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: _____

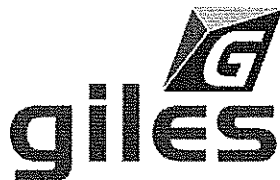
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3/2/15



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Giles Chemical, a division of Premier Magnesia, LLC.

102 Commerce Street Waynesville, NC 28786

Phone: 828-452-4784 Fax: 828-452-2786

USP Certificate of Analysis

Release Date: 11/15/2014

CUSTOMER: _____

CUST. REF: _____

SHIP DATE: _____

PRODUCT: Magnesium Sulfate - USP

TRAILER NUMBER: _____

SHELF LIFE: 3 Years

BILL OF LADING #: _____

LOT NUMBER: 6014

PO NUMBER #: _____

SHIPPER: _____

MANUFACTURED: _____

CUST. SERV.: _____

EXPIRATION: _____

I certify that this material meets all the requirements of the Giles Chemical sales specifications and the United States Pharmacopeia 35. Periodic testing has shown the samples to be consistently free of volatile organic impurities. Giles Chemical magnesium sulfate is manufactured under the guidelines of Current Good Manufacturing Practices (cGMP).

EPSOM SALT, Magnesium Sulfate - Heptahydrate, USP

METHOD	TEST	LOWER	UPPER	Test Results
VISUAL	Appearance	~~	~~	Clear
USP35	Chloride as Cl (%)	~~	0.014	< 0.014%
USP35	Heavy Metals As Pb (%)	~~	0.001	< 0.001%
USP35	Ignition Loss (%)	40.00	52.00	51.23%
USP35	Iron (ppm)	~~	20.00	< 20.00 ppm
USP35	MgSO ₄ (Anhydrous wt. %)	99.00	100.50	100.02%
USP35	MgSO ₄ (As is basis, %)	48.30	52.00	48.81%
USP35	pH 5% Solution	5.00	9.20	5.00
USP35	Selenium (%)	~~	0.003	< 0.003%
USP35	Mg ²⁺ ID			Present
USP35	SO ₄ ²⁻ ID			Present

CONTACT:

ANALYST:

Quality Assurance Laboratory

SIGNATURE ON FILE

John Safi - Chemist

828-452-4784 ext. 31



Giles Chemical, a division of Premier Magnesia, LLC.

102 Commerce Street Waynesville, NC 28786

Phone: 828-452-4784 Fax: 828-452-2786

USP Certificate of Analysis

Release Date: 11/22/2014

CUSTOMER: _____

CUST. REF: _____ SHIP DATE: _____

PRODUCT: Magnesium Sulfate - USP TRAILER NUMBER: _____

SHELF LIFE: 3 Years BILL OF LADING #: _____

LOT NUMBER: 6114 PO NUMBER #: _____

SHIPPER: _____ MANUFACTURED: _____

CUST. SERV.: _____ EXPIRATION: _____

I certify that this material meets all the requirements of the Giles Chemical sales specifications and the United States Pharmacopeia 35. Periodic testing has shown the samples to be consistently free of volatile organic impurities. Giles Chemical magnesium sulfate is manufactured under the guidelines of Current Good Manufacturing Practices (cGMP).

EPSOM SALT, Magnesium Sulfate - Heptahydrate, USP

METHOD	TEST	LOWER	UPPER	Test Results
VISUAL	Appearance	~~	~~	Clear
USP35	Chloride as Cl (%)	~~	0.014	< 0.014%
USP35	Heavy Metals As Pb (%)	~~	0.001	< 0.001%
USP35	Ignition Loss (%)	40.00	52.00	51.00%
USP35	Iron (ppm)	~~	20.00	< 20.00 ppm
USP35	MgSO ₄ (Anhydrous wt. %)	99.00	100.50	99.75%
USP35	MgSO ₄ (As is basis, %)	48.30	52.00	48.68%
USP35	pH 5% Solution	5.00	9.20	8.11
USP35	Selenium (%)	~~	0.003	< 0.003%
USP35	Mg ²⁺ ID			Present
USP35	SO ₄ ²⁻ ID			Present

CONTACT:

Quality Assurance Laboratory

John Safi - Chemist

828-452-4784 ext. 31

ANALYST:

SIGNATURE ON FILE



Giles Chemical, a division of Premier Magnesia, LLC.

102 Commerce Street Waynesville, NC 28786

Phone: 828-452-4784 Fax: 828-452-2786

USP Certificate of Analysis

Release Date: 11/29/2014

CUSTOMER: _____

CUST. REF: _____

SHIP DATE: _____

PRODUCT: Magnesium Sulfate - USP

TRAILER NUMBER: _____

SHELF LIFE: 3 Years

BILL OF LADING #: _____

LOT NUMBER: 6214

PO NUMBER #: _____

SHIPPER: _____

MANUFACTURED: _____

CUST. SERV.: _____

EXPIRATION: _____

I certify that this material meets all the requirements of the Giles Chemical sales specifications and the United States Pharmacopeia 35. Periodic testing has shown the samples to be consistently free of volatile organic impurities. Giles Chemical magnesium sulfate is manufactured under the guidelines of Current Good Manufacturing Practices (cGMP).

EPSOM SALT, Magnesium Sulfate - Heptahydrate, USP

METHOD	TEST	LOWER	UPPER	Test Results
VISUAL	Appearance	~	~	Clear
USP35	Chloride as Cl (%)	~	0.014	< 0.014%
USP35	Heavy Metals As Pb (%)	~	0.001	< 0.001%
USP35	Ignition Loss (%)	40.00	52.00	50.84%
USP35	Iron (ppm)	~	20.00	< 20.00 ppm
USP35	MgSO ₄ (Anhydrous wt. %)	99.00	100.50	99.71%
USP35	MgSO ₄ (As is basis, %)	48.30	52.00	48.66%
USP35	pH 5% Solution	5.00	9.20	6.78
USP35	Selenium (%)	~	0.003	< 0.003%
USP35	Mg ²⁺ ID			Present
USP35	SO ₄ ²⁻ ID			Present

CONTACT:

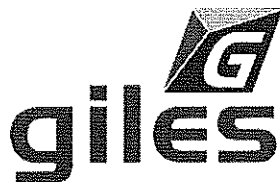
ANALYST:

Quality Assurance Laboratory

SIGNATURE ON FILE

John Safi - Chemist

828-452-4784 ext. 31



Giles Chemical, a division of Premier Magnesia, LLC.

102 Commerce Street Waynesville, NC 28786

Phone: 828-452-4784 Fax: 828-452-2786

USP Certificate of Analysis

Release Date: 12/6/2014

CUSTOMER: _____

CUST. REF: _____ SHIP DATE: _____

PRODUCT: **Magnesium Sulfate - USP** TRAILER NUMBER: _____

SHELF LIFE: **3 Years** BILL OF LADING #: _____

LOT NUMBER: **6314** PO NUMBER #: _____

SHIPPER: _____ MANUFACTURED: _____

CUST. SERV.: _____ EXPIRATION: _____

I certify that this material meets all the requirements of the Giles Chemical sales specifications and the United States Pharmacopeia 35. Periodic testing has shown the samples to be consistently free of volatile organic impurities. Giles Chemical magnesium sulfate is manufactured under the guidelines of Current Good Manufacturing Practices (cGMP).

EPSOM SALT, Magnesium Sulfate - Heptahydrate, USP

METHOD	TEST	LOWER	UPPER	Test Results
VISUAL	Appearance	~~	~~	Clear
USP35	Chloride as Cl (%)	~~	0.014	< 0.014%
USP35	Heavy Metals As Pb (%)	~~	0.001	< 0.001%
USP35	Ignition Loss (%)	40.00	52.00	51.21%
USP35	Iron (ppm)	~~	20.00	< 20.00 ppm
USP35	MgSO ₄ (Anhydrous wt. %)	99.00	100.50	99.85%
USP35	MgSO ₄ (As is basis, %)	48.30	52.00	48.73%
USP35	pH 5% Solution	5.00	9.20	8.11
USP35	Selenium (%)	~~	0.003	< 0.003%
USP35	Mg ²⁺ ID			Present
USP35	SO ₄ ²⁻ ID			Present

CONTACT:

Quality Assurance Laboratory

John Safi - Chemist

828-452-4784 ext. 31

ANALYST:

SIGNATURE ON FILE



Giles Chemical, a division of Premier Magnesia, LLC.

102 Commerce Street Waynesville, NC 28786

Phone: 828-452-4784 Fax: 828-452-2786

USP Certificate of Analysis

Release Date: 12/13/2014

CUSTOMER: _____

CUST. REF: _____

SHIP DATE: _____

PRODUCT: Magnesium Sulfate - USP

TRAILER NUMBER: _____

SHELF LIFE: 3 Years

BILL OF LADING #: _____

LOT NUMBER: 6414

PO NUMBER #: _____

SHIPPER: _____

MANUFACTURED: _____

CUST. SERV.: _____

EXPIRATION: _____

I certify that this material meets all the requirements of the Giles Chemical sales specifications and the United States Pharmacopeia 35. Periodic testing has shown the samples to be consistently free of volatile organic impurities. Giles Chemical magnesium sulfate is manufactured under the guidelines of Current Good Manufacturing Practices (cGMP).

EPSOM SALT, Magnesium Sulfate - Heptahydrate, USP

METHOD	TEST	LOWER	UPPER	Test Results
VISUAL	Appearance	~~	~~	Clear
USP35	Chloride as Cl (%)	~~	0.014	< 0.014%
USP35	Heavy Metals As Pb (%)	~~	0.001	< 0.001%
USP35	Ignition Loss (%)	40.00	52.00	50.96%
USP35	Iron (ppm)	~~	20.00	< 20.00 ppm
USP35	MgSO ₄ (Anhydrous wt. %)	99.00	100.50	99.42%
USP35	MgSO ₄ (As is basis, %)	48.30	52.00	48.52%
USP35	pH 5% Solution	5.00	9.20	6.82
USP35	Selenium (%)	~~	0.003	< 0.003%
USP35	Mg ²⁺ ID			Present
USP35	SO ₄ ²⁻ ID			Present

CONTACT:

ANALYST:

Quality Assurance Laboratory

SIGNATURE ON FILE

John Safi - Chemist

828-452-4784 ext. 31



Giles Chemical, a division of Premier Magnesia, LLC.

102 Commerce Street Waynesville, NC 28786

Phone: 828-452-4784 Fax: 828-452-2786

USP Certificate of Analysis

Release Date: 12/22/2014

CUSTOMER: _____

CUST. REF: _____

SHIP DATE: _____

PRODUCT: Magnesium Sulfate - USP

TRAILER NUMBER: _____

SHELF LIFE: 3 Years

BILL OF LADING #: _____

LOT NUMBER: 6514

PO NUMBER #: _____

SHIPPER: _____

MANUFACTURED: _____

CUST. SERV.: _____

EXPIRATION: _____

I certify that this material meets all the requirements of the Giles Chemical sales specifications and the United States Pharmacopeia 35. Periodic testing has shown the samples to be consistently free of volatile organic impurities. Giles Chemical magnesium sulfate is manufactured under the guidelines of Current Good Manufacturing Practices (cGMP).

EPSOM SALT, Magnesium Sulfate - Heptahydrate, USP

METHOD	TEST	LOWER	UPPER	Test Results
VISUAL	Appearance	~~	~~	Clear
USP35	Chloride as Cl (%)	~~	0.014	< 0.014%
USP35	Heavy Metals As Pb (%)	~~	0.001	< 0.001%
USP35	Ignition Loss (%)	40.00	52.00	50.98%
USP35	Iron (ppm)	~~	20.00	< 20.00 ppm
USP35	MgSO ₄ (Anhydrous wt. %)	99.00	100.50	99.78%
USP35	MgSO ₄ (As is basis, %)	48.30	52.00	48.69%
USP35	pH 5% Solution	5.00	9.20	6.59
USP35	Selenium (%)	~~	0.003	< 0.003%
USP35	Mg ²⁺ ID			Present
USP35	SO ₄ ²⁻ ID			Present

CONTACT:

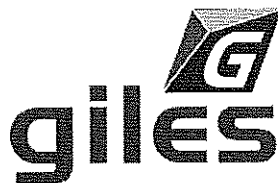
ANALYST:

Quality Assurance Laboratory

SIGNATURE ON FILE

John Safi - Chemist

828-452-4784 ext. 31



Giles Chemical, a division of Premier Magnesia, LLC.

102 Commerce Street Waynesville, NC 28786

Phone: 828-452-4784 Fax: 828-452-2786

USP Certificate of Analysis

Release Date: 12/29/2014

CUSTOMER: _____

CUST. REF: _____

SHIP DATE: _____

PRODUCT: Magnesium Sulfate - USP

TRAILER NUMBER: _____

SHELF LIFE: 3 Years

BILL OF LADING #: _____

LOT NUMBER: 6613

PO NUMBER #: _____

SHIPPER: _____

MANUFACTURED: _____

CUST. SERV.: _____

EXPIRATION: _____

I certify that this material meets all the requirements of the Giles Chemical sales specifications and the United States Pharmacopeia 35. Periodic testing has shown the samples to be consistently free of volatile organic impurities. Giles Chemical magnesium sulfate is manufactured under the guidelines of Current Good Manufacturing Practices (cGMP).

EPSOM SALT, Magnesium Sulfate - Heptahydrate, USP

METHOD	TEST	LOWER	UPPER	Test Results
VISUAL	Appearance	~~	~~	Clear
USP35	Chloride as Cl (%)	~~	0.014	< 0.014%
USP35	Heavy Metals As Pb (%)	~~	0.001	< 0.001%
USP35	Ignition Loss (%)	40.00	52.00	50.32%
USP35	Iron (ppm)	~~	20.00	< 20.00 ppm
USP35	MgSO ₄ (Anhydrous wt. %)	99.00	100.50	99.54%
USP35	MgSO ₄ (As is basis, %)	48.30	52.00	48.57%
USP35	pH 5% Solution	5.00	9.20	5.51
USP35	Selenium (%)	~~	0.003	< 0.003%
USP35	Mg ²⁺ ID			Present
USP35	SO ₄ ²⁻ ID			Present

CONTACT:

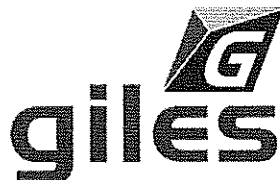
ANALYST:

Quality Assurance Laboratory

SIGNATURE ON FILE

John Safi - Chemist

828-452-4784 ext. 31



Giles Chemical, a division of Premier Magnesia, LLC.

102 Commerce Street Waynesville, NC 28786

Phone: 828-452-4784 Fax: 828-452-2786

USP Certificate of Analysis

Release Date: 1/10/2015

CUSTOMER: _____

CUST. REF: _____

SHIP DATE: _____

PRODUCT: Magnesium Sulfate - USP

TRAILER NUMBER: _____

SHELF LIFE: 3 Years

BILL OF LADING #: _____

LOT NUMBER: 0215

PO NUMBER #: _____

CARRIER: _____

MANUFACTURED: _____

CUST. CONTACT: _____

EXPIRATION: _____

I certify that this material meets all the requirements of the Giles Chemical sales specifications and the United States Pharmacopeia 35. Periodic testing has shown the samples to be consistently free of volatile organic impurities. Giles Chemical magnesium sulfate is manufactured under the guidelines of Current Good Manufacturing Practices (cGMP).

EPSOM SALT, Magnesium Sulfate - Heptahydrate, USP

METHOD	TEST	LOWER	UPPER	Test Results
VISUAL	Appearance	~~	~~	Clear
USP35	Chloride as Cl (%)	~~	0.014	< 0.014%
USP35	Heavy Metals As Pb (%)	~~	0.001	< 0.001%
USP35	Ignition Loss (%)	40.00	52.00	50.83%
USP35	Iron (ppm)	~~	20.00	< 20.00 ppm
USP35	MgSO ₄ (Anhydrous wt. %)	99.00	100.50	100.40%
USP35	MgSO ₄ (As is basis, %)	48.30	52.00	49.00%
USP35	pH 5% Solution	5.00	9.20	6.86
USP35	Selenium (%)	~~	0.003	< 0.003%
USP35	Mg ²⁺ ID			Present
USP35	SO ₄ ²⁻ ID			Present

CONTACT:

ANALYST:

Quality Assurance Laboratory

SIGNATURE ON FILE

John Safi - Chemist

828-452-4784 ext. 31



Giles Chemical, a division of Premier Magnesia, LLC.

102 Commerce Street Waynesville, NC 28786

Phone: 828-452-4784 Fax: 828-452-2786

USP Certificate of Analysis

Release Date: 1/17/2015

CUSTOMER: _____

CUST. REF: _____

PRODUCT: Magnesium Sulfate - USP

SHELF LIFE: 3 Years

LOT NUMBER: 0315

SHIPPER: _____

CUST. SERV.: _____

SHIP DATE: _____

TRAILER NUMBER: _____

BILL OF LADING #: _____

PO NUMBER #: _____

MANUFACTURED: _____

EXPIRATION: _____

I certify that this material meets all the requirements of the Giles Chemical sales specifications and the United States Pharmacopeia 35. Periodic testing has shown the samples to be consistently free of volatile organic impurities. Giles Chemical magnesium sulfate is manufactured under the guidelines of Current Good Manufacturing Practices (cGMP).

EPSOM SALT, Magnesium Sulfate - Heptahydrate, USP

METHOD	TEST	LOWER	UPPER	Test Results
VISUAL	Appearance	~~	~~	Clear
USP35	Chloride as Cl (%)	~~	0.014	< 0.014%
USP35	Heavy Metals As Pb (%)	~~	0.001	< 0.001%
USP35	Ignition Loss (%)	40.00	52.00	50.81%
USP35	Iron (ppm)	~~	20.00	< 20.00 ppm
USP35	MgSO ₄ (Anhydrous wt. %)	99.00	100.50	100.31%
USP35	MgSO ₄ (As is basis, %)	48.30	52.00	48.95%
USP35	pH 5% Solution	5.00	9.20	8.18
USP35	Selenium (%)	~~	0.003	< 0.003%
USP35	Mg ²⁺ ID			Present
USP35	SO ₄ ²⁻ ID			Present

CONTACT:

Quality Assurance Laboratory

John Safi - Chemist

828-452-4784 ext. 31

ANALYST:

SIGNATURE ON FILE



Giles Chemical, a division of Premier Magnesia, LLC.

102 Commerce Street Waynesville, NC 28786

Phone: 828-452-4784 Fax: 828-452-2786

USP Certificate of Analysis

Release Date: 1/24/2015

CUSTOMER: _____

CUST. REF: _____ SHIP DATE: _____

PRODUCT: **Magnesium Sulfate - USP** TRAILER NUMBER: _____

SHELF LIFE: 3 Years BILL OF LADING #: _____

LOT NUMBER: **0415** PO NUMBER #: _____

SHIPPER: _____ MANUFACTURED: _____

CUST. SERV.: _____ EXPIRATION: _____

I certify that this material meets all the requirements of the Giles Chemical sales specifications and the United States Pharmacopeia 35. Periodic testing has shown the samples to be consistently free of volatile organic impurities. Giles Chemical magnesium sulfate is manufactured under the guidelines of Current Good Manufacturing Practices (cGMP).

EPSOM SALT, Magnesium Sulfate - Heptahydrate, USP

METHOD	TEST	LOWER	UPPER	Test Results
VISUAL	Appearance	~~	~~	Clear
USP35	Chloride as Cl (%)	~~	0.014	< 0.014%
USP35	Heavy Metals As Pb (%)	~~	0.001	< 0.001%
USP35	Ignition Loss (%)	40.00	52.00	50.91%
USP35	Iron (ppm)	~~	20.00	< 20.00 ppm
USP35	MgSO ₄ (Anhydrous wt. %)	99.00	100.50	99.66%
USP35	MgSO ₄ (As is basis, %)	48.30	52.00	48.63%
USP35	pH 5% Solution	5.00	9.20	8.97
USP35	Selenium (%)	~~	0.003	< 0.003%
USP35	Mg ²⁺ ID			Present
USP35	SO ₄ ²⁻ ID			Present

CONTACT:

Quality Assurance Laboratory

John Safi - Chemist

828-452-4784 ext. 31

ANALYST:

SIGNATURE ON FILE



Giles Chemical, a division of Premier Magnesia, LLC.

102 Commerce Street Waynesville, NC 28786

Phone: 828-452-4784 Fax: 828-452-2786

USP Certificate of Analysis

Release Date: 1/31/2015

CUSTOMER: _____

CUST. REF: _____

PRODUCT: Magnesium Sulfate - USP

SHELF LIFE: 3 Years

LOT NUMBER: 0515

SHIPPER: _____

CUST. SERV.: _____

SHIP DATE: _____

TRAILER NUMBER: _____

BILL OF LADING #: _____

PO NUMBER #: _____

MANUFACTURED: _____

EXPIRATION: _____

I certify that this material meets all the requirements of the Giles Chemical sales specifications and the United States Pharmacopeia 35. Periodic testing has shown the samples to be consistently free of volatile organic impurities. Giles Chemical magnesium sulfate is manufactured under the guidelines of Current Good Manufacturing Practices (cGMP).

EPSOM SALT, Magnesium Sulfate - Heptahydrate, USP

METHOD	TEST	LOWER	UPPER	Test Results
VISUAL	Appearance	~~	~~	Clear
USP35	Chloride as Cl (%)	~~	0.014	< 0.014%
USP35	Heavy Metals As Pb (%)	~~	0.001	< 0.001%
USP35	Ignition Loss (%)	40.00	52.00	51.15%
USP35	Iron (ppm)	~~	20.00	< 20.00 ppm
USP35	MgSO ₄ (Anhydrous wt. %)	99.00	100.50	100.45%
USP35	MgSO ₄ (As is basis, %)	48.30	52.00	49.02%
USP35	pH 5% Solution	5.00	9.20	8.82
USP35	Selenium (%)	~~	0.003	< 0.003%
USP35	Mg ²⁺ ID			Present
USP35	SO ₄ ²⁻ ID			Present

CONTACT:

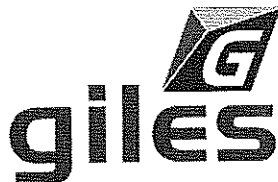
Quality Assurance Laboratory

John Safi - Chemist

828-452-4784 ext. 31

ANALYST:

SIGNATURE ON FILE



Giles Chemical, a division of Premier Magnesia, LLC.

102 Commerce Street Waynesville, NC 28786

Phone: 828-452-4784 Fax: 828-452-2786

USP Certificate of Analysis

Release Date: 2/6/2015

CUSTOMER: _____

CUST. REF: _____ SHIP DATE: _____

PRODUCT: **Magnesium Sulfate - USP** TRAILER NUMBER: _____

SHELF LIFE: 3 Years BILL OF LADING #: _____

LOT NUMBER: **0615** PO NUMBER #: _____

SHIPPER: _____ MANUFACTURED: _____

CUST. SERV.: _____ EXPIRATION: _____

I certify that this material meets all the requirements of the Giles Chemical sales specifications and the United States Pharmacopeia 35. Periodic testing has shown the samples to be consistently free of volatile organic impurities. Giles Chemical magnesium sulfate is manufactured under the guidelines of Current Good Manufacturing Practices (cGMP).

EPSOM SALT, Magnesium Sulfate - Heptahydrate, USP

METHOD	TEST	LOWER	UPPER	Test Results
VISUAL	Appearance	~~	~~	Clear
USP35	Chloride as Cl (%)	~~	0.014	< 0.014%
USP35	Heavy Metals As Pb (%)	~~	0.001	< 0.001%
USP35	Ignition Loss (%)	40.00	52.00	50.74%
USP35	Iron (ppm)	~~	20.00	< 20.00 ppm
USP35	MgSO ₄ (Anhydrous wt. %)	99.00	100.50	100.31%
USP35	MgSO ₄ (As is basis, %)	48.30	52.00	48.95%
USP35	pH 5% Solution	5.00	9.20	7.86
USP35	Selenium (%)	~~	0.003	< 0.003%
USP35	Mg ²⁺ ID			Present
USP35	SO ₄ ²⁻ ID			Present

CONTACT:

Quality Assurance Laboratory

John Safi - Chemist

828-452-4784 ext. 31

ANALYST:

SIGNATURE ON FILE



Giles Chemical, a division of Premier Magnesia, LLC.

102 Commerce Street Waynesville, NC 28786

Phone: 828-452-4784 Fax: 828-452-2786

USP Certificate of Analysis

Release Date: 2/14/2015

CUSTOMER: _____

CUST. REF: _____ SHIP DATE: _____

PRODUCT: Magnesium Sulfate - USP TRAILER NUMBER: _____

SHELF LIFE: 3 Years BILL OF LADING #: _____

LOT NUMBER: 0715 PO NUMBER #: _____

SHIPPER: _____ MANUFACTURED: _____

CUST. SERV.: _____ EXPIRATION: _____

I certify that this material meets all the requirements of the Giles Chemical sales specifications and the United States Pharmacopeia 35. Periodic testing has shown the samples to be consistently free of volatile organic impurities. Giles Chemical magnesium sulfate is manufactured under the guidelines of Current Good Manufacturing Practices (cGMP).

EPSOM SALT, Magnesium Sulfate - Heptahydrate, USP

METHOD	TEST	LOWER	UPPER	Test Results
VISUAL	Appearance	~~	~~	Clear
USP35	Chloride as Cl (%)	~~	0.014	< 0.014%
USP35	Heavy Metals As Pb (%)	~~	0.001	< 0.001%
USP35	Ignition Loss (%)	40.00	52.00	51.28%
USP35	Iron (ppm)	~~	20.00	< 20.00 ppm
USP35	MgSO ₄ (Anhydrous wt. %)	99.00	100.50	100.40%
USP35	MgSO ₄ (As is basis, %)	48.30	52.00	49.00%
USP35	pH 5% Solution	5.00	9.20	8.92
USP35	Selenium (%)	~~	0.003	< 0.003%
USP35	Mg ²⁺ ID			Present
USP35	SO ₄ ²⁻ ID			Present

CONTACT:

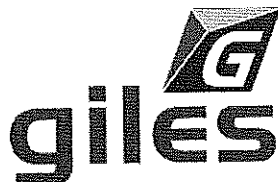
Quality Assurance Laboratory

John Safi - Chemist

828-452-4784 ext. 31

ANALYST:

SIGNATURE ON FILE



Giles Chemical, a division of Premier Magnesia, LLC.

102 Commerce Street Waynesville, NC 28786

Phone: 828-452-4784 Fax: 828-452-2786

USP Certificate of Analysis

Release Date: 2/21/2015

CUSTOMER: _____

CUST. REF: _____ SHIP DATE: _____

PRODUCT: **Magnesium Sulfate - USP** TRAILER NUMBER: _____

SHELF LIFE: 3 Years BILL OF LADING #: _____

LOT NUMBER: **0815** PO NUMBER #: _____

SHIPPER: _____ MANUFACTURED: _____

CUST. SERV.: _____ EXPIRATION: _____

I certify that this material meets all the requirements of the Giles Chemical sales specifications and the United States Pharmacopeia 35. Periodic testing has shown the samples to be consistently free of volatile organic impurities. Giles Chemical magnesium sulfate is manufactured under the guidelines of Current Good Manufacturing Practices (cGMP).

EPSOM SALT, Magnesium Sulfate - Heptahydrate, USP

METHOD	TEST	LOWER	UPPER	Test Results
VISUAL	Appearance	~~	~~	Clear
USP35	Chloride as Cl (%)	~~	0.014	< 0.014%
USP35	Heavy Metals As Pb (%)	~~	0.001	< 0.001%
USP35	Ignition Loss (%)	40.00	52.00	51.02%
USP35	Iron (ppm)	~~	20.00	< 20.00 ppm
USP35	MgSO ₄ (Anhydrous wt. %)	99.00	100.50	99.97%
USP35	MgSO ₄ (As is basis, %)	48.30	52.00	48.79%
USP35	pH 5% Solution	5.00	9.20	8.50
USP35	Selenium (%)	~~	0.003	< 0.003%
USP35	Mg ²⁺ ID			Present
USP35	SO ₄ ²⁻ ID			Present

CONTACT:

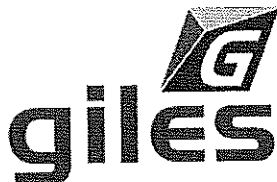
Quality Assurance Laboratory

John Safi - Chemist

828-452-4784 ext. 31

ANALYST:

SIGNATURE ON FILE



Giles Chemical, a division of Premier Magnesia, LLC.

102 Commerce Street Waynesville, NC 28786

Phone: 828-452-4784 Fax: 828-452-2786

USP Certificate of Analysis

Release Date: 2/28/2015

CUSTOMER: _____

CUST. REF: _____ SHIP DATE: _____

PRODUCT: Magnesium Sulfate - USP TRAILER NUMBER: _____

SHELF LIFE: 3 Years BILL OF LADING #: _____

LOT NUMBER: 0915 PO NUMBER #: _____

SHIPPER: _____ MANUFACTURED: _____

CUST. SERV.: _____ EXPIRATION: _____

I certify that this material meets all the requirements of the Giles Chemical sales specifications and the United States Pharmacopeia 35. Periodic testing has shown the samples to be consistently free of volatile organic impurities. Giles Chemical magnesium sulfate is manufactured under the guidelines of Current Good Manufacturing Practices (cGMP).

EPSOM SALT, Magnesium Sulfate - Heptahydrate, USP

METHOD	TEST	LOWER	UPPER	Test Results
VISUAL	Appearance	~~	~~	Clear
USP35	Chloride as Cl (%)	~~	0.014	< 0.014%
USP35	Heavy Metals As Pb (%)	~~	0.001	< 0.001%
USP35	Ignition Loss (%)	40.00	52.00	51.01%
USP35	Iron (ppm)	~~	20.00	< 20.00 ppm
USP35	MgSO ₄ (Anhydrous wt. %)	99.00	100.50	99.78%
USP35	MgSO ₄ (As is basis, %)	48.30	52.00	48.69%
USP35	pH 5% Solution	5.00	9.20	8.79
USP35	Selenium (%)	~~	0.003	< 0.003%
USP35	Mg ²⁺ ID			Present
USP35	SO ₄ ²⁻ ID			Present

CONTACT:

Quality Assurance Laboratory

John Safi - Chemist

828-452-4784 ext. 31

ANALYST:

SIGNATURE ON FILE