
	GILES CHEMICAL ~ PREMIER MAGNESIA		
	Company Procedure		
	Title: USP Stability Testing	Number: L12-PR-100-010	
	Owner: Stephen Ballew	Revision: 0	
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## 1.0 Purpose

- 1.1 To assess the stability characteristics of Giles Chemical magnesium sulfate heptahydrate. Stability studies include an evaluation of the physical and chemical properties to determine temperature sensitivity and susceptibility to degradation over time.

## 2.0 Scope

- 2.1 Results of on-going stability testing are used to confirm appropriate storage conditions and expiry dates.
- 2.2 The standard tests for stability include: Real-time long-term stability testing at room temperature and accelerated stability testing at  $45 \pm 3$  °C (3 months at 45 °C is equivalent to 2 years of shelf life).

## 3.0 Responsibility

- 3.1 The Quality Associate is responsible for this procedure.

## 4.0 Safety Considerations

- 4.1 Steel toed shoes and safety glasses are required at a minimum in the Manufacturing and Repackaging areas when collecting samples. Safety is a condition of employment. Employees are not authorized to work in an unsafe manner and are prohibited from harming the environment of the facility or community.



## 5.0 Materials/Equipment

- 5.1 Annually Calibrated Oven
- 5.2 Laboratory Notebook

## 6.0 Procedure

### 6.1 USP Testing Procedures for Stability

- 6.1.1 *USP Identification of Magnesium Sulfate* L12-PR-100-001
- 6.1.2 *USP pH* L12-PR-100-002
- 6.1.3 *USP Loss on Ignition* L12-PR-100-003
- 6.1.4 *USP Chloride* L12-PR-100-004
- 6.1.5 *USP Iron* L12-PR-100-005

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6.1.6 *USP Heavy Metals* L12-PR-100-006

6.1.7 *USP Selenium* L12-PR-100-007

6.1.8 *USP Assay* L12-PR-100-008



## 6.2 Real-time Long-term Stability Testing

- 6.2.1 All results are recorded in the appropriate laboratory notebook and on *USP Stability Testing Summary Worksheet* Q12-PR-100-F010.
- 6.2.2 Use sealed pouches or other final packaging as appropriate.
- 6.2.3 Record the date, lot number and initials on the pouch.
- 6.2.4 Perform each USP testing procedure for stability in section 6.1 and record the results.
- 6.2.5 Evaluate sample for odor, appearance and caking and record all observations.
- 6.2.6 Seal pouch and place sample in segregated stability testing area away from contamination.
- 6.2.7 After one year, perform steps 6.2.4 – 6.2.6 again and record results.
- 6.2.8 Repeat step 6.2.7 for the next three years for a total of four years of stability data.

## 6.3 Accelerated Stability Testing @ 45 °C ± 3 °C

- 6.3.1 All results are recorded in the appropriate laboratory notebook and on *USP Stability Testing Summary Worksheet* Q12-PR-100-F010.
- 6.3.2 Use sealed pouches or other final packaging as appropriate.
- 6.3.3 Record date, lot number and initials on package.
- 6.3.4 Perform each USP testing procedure for stability in section 6.1 and record the results.
- 6.3.5 Evaluate sample for odor, appearance and caking and record all observations.
- 6.3.6 Make sure that the oven is set for 45 °C ± 3 °C.
- 6.3.7 Seal pouch and place sample in calibrated oven.
- 6.3.8 After three months, perform steps 6.3.4 – 6.3.7 again and record the results.
- 6.3.9 Repeat steps 6.3.4 – 6.3.7 again after six months and record the results.

## 6.4 Disposal of Stability Samples

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- 6.4.1 After all stability testing has been performed samples shall be disposed of properly.
- 6.4.2 Salt should be disposed of in the Pour Back area or diluted in the sink and poured down the drain.

## 6.5 Evaluation and Retention of Data

- 6.5.1 Stability data shall be evaluated to justify appropriate storage conditions and expiry dates.
- 6.5.2 Data for stability testing will be recorded in the appropriate laboratory notebook and maintained by the Quality Unit. *USP Stability Testing Summary Worksheet* Q12-PR-100-F010 shall be retained in a binder and maintained by the Quality Unit.

## 7.0 Reference Documents

- 7.1 *USP Stability Testing Summary Worksheet* Q12-PR-100-F010
- 7.2 *USP Identification of Magnesium Sulfate* L12-PR-100-001
- 7.3 *USP pH* L12-PR-100-002
- 7.4 *USP Loss on Ignition* L12-PR-100-003
- 7.5 *USP Chloride* L12-PR-100-004
- 7.6 *USP Iron* L12-PR-100-005
- 7.7 *USP Heavy Metals* L12-PR-100-006
- 7.8 *USP Selenium* L12-PR-100-007
- 7.9 *USP Assay* L12-PR-100-008

## 8.0 Amendment Record

Revision Number	Revision Date	Revision Author	Revision Description
0	08/16/12	SB	New Document