1.0 Purpose

The purpose of this procedure is to outline how to assess the stability characteristics of Magnesium Sulfate Heptahydrate. Stability studies include an evaluation of the physical and chemical properties to determine temperature sensitivity and susceptibility to degradation over time. Results of on-going stability testing are used to confirm appropriate storage conditions and expiry dates.
The standard tests for stability include:

- Real-time long-term stability testing at 25± 2 °C (60%± 5% RH) unless simulating conditions specified by customer.
- Accelerated stability testing at 40± 2 °C (75%± 5% RH) Note: 3 months at 40± 2 °C is equivalent to 2 years of shelf life.

2.0 Scope

This procedure applies to all Giles Chemical finished product. All Stability testing is performed by the Quality Assurance laboratory.

3.0 Responsibility

QA Lab personnel are responsible for performing this procedure.

4.0 Safety Considerations

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

- Annually Calibrated Oven
- Laboratory Notebook

6.0 Procedure

6.1 USP Testing Procedures for Stability

1. *USP Identification of Magnesium Sulfate (L12-PR-100-001)*
2. *USP pH (L12-PR-100-002)*

3. *USP Loss on Ignition (L12-PR-100-003)*
4. *USP Chloride (L12-PR-100-004)*
5. *USP Iron (L12-PR-100-005)*
6. *USP Heavy Metals (L12-PR-100-006)*
7. *USP Selenium (L12-PR-100-007)*
8. *USP Assay (L12-PR-100-008)*

6.2 Real-time Long-term Stability Testing @ 25± 2 °C (60%± 5% RH) unless simulating conditions specified by customer

1. All results are recorded in the appropriate laboratory notebook and on *USP Stability Testing Summary Worksheet (Q12-PR-100-F010)*.
2. Use sealed pouches or other final packaging as appropriate.
3. Record the date, lot number and initials on the pouch.
4. Perform each USP testing procedure for stability in section 6.1 and record the results.
5. Evaluate sample for odor, appearance and caking and record all observations.
6. Close pouch and place sample on segregated stability testing area away from contamination.
7. Stability testing is performed initially, then every three months for the first year, then every six months for the second year, and then annually thereafter.

6.3 Accelerated Stability Testing @ 40 ± 2 °C (75%± 5% RH)

1. All results are recorded in the appropriate laboratory notebook and on *USP Stability Testing Summary Worksheet (L12-PR-100-F010)*.
2. Use sealed pouches or other final packaging as appropriate.
3. Record date and lot number and initials on package.
4. Perform each USP testing procedure for stability in section 6.1 and record the results.
5. Evaluate sample for odor, appearance and caking and record all observations.
6. Press “Stop” on the oven control panel before opening the door.
7. Close pouch and place sample in oven.

8. Make sure that the oven is set for 40± 2 °C (75%± 5% RH).
9. Close the door and press "Run" on the oven.
10. After three months, perform steps 6.3.3 – 6.3.8 again and record the results.
11. Repeat steps 3 – 8 again after six months and record the results.

6.4 Disposal of Stability Samples

After all stability testing has been performed samples shall be disposed of properly in trash dumpster.

6.5 Evaluation and Retention of Data

1. Stability data shall be evaluated to justify appropriate storage conditions and expiry dates.
2. Data for stability testing will be recorded in the appropriate laboratory notebook and maintained by the Quality Unit. *USP Stability Testing Summary Worksheet (L12-PR-100-F010)* shall be retained in a binder and maintained by the Quality Unit for a period of at least 5 years.

7.0 Reference Documents

1. *USP Stability Testing Summary Worksheet (L12-PR-100-F010)*
2. *USP Identification of Magnesium Sulfate (L12-PR-100-001)*
3. *USP pH (L12-PR-100-002)*
4. *USP Loss on Ignition (L12-PR-100-003)*
5. *USP Chloride (L12-PR-100-004)*
6. *USP Iron (L12-PR-100-005)*
7. *USP Heavy Metals (L12-PR-100-006)*
8. *USP Selenium (L12-PR-100-007)*
9. *USP Assay (L12-PR-100-008)*

8.0 Change Information

New Document