1.0 Purpose

The purpose of this procedure is to describe how to properly determine the pH of magnesium sulfate heptahydrate in solution following USP Monograph: Magnesium Sulfate, and General Chapter <791>.

2.0 Scope

This procedure applies to all USP testing including but not limited to USP lot change, USP Repack testing, stability testing, and any time USP quality needs to be verified. All USP testing is performed in the Quality Assurance laboratory.

3.0 Responsibility

QA Lab personnel are responsible for performing this procedure and completing all USP testing.

4.0 Safety Considerations

Proper PPE should be worn at all times including steel-toed shoes, safety glasses, and a lab coat.

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

- pH Meter System
- Analytical Balance
- 150 ml Beaker
- Supply of De-ionized Water
- Magnetic Stirring Plate
- Magnetic Stirring Bars
- Lint-free wipe
- Weigh Paper or Weigh boat

6.0 Procedure

The pH system should be calibrated once per working day before use using *USP pH Meter Calibration and Maintenance (L12-PR-100-015)*.

1. Weigh approximately 5.00 g of the sample on a piece of weigh paper using the analytical balance.

2. To a 150 ml beaker add 100 ml of H_2O.
3. Place the beaker on the magnetic stirring plate and add the sample.
4. Add a stir bar to the beaker and turn stirring plate on.
5. Remove remove probe tip from storage solution, rinse the tip with de-ionized water, and dry with lint-free wipe.
6. When the sample has completely dissolved, place the probe in the solution and turn on the pH meter.
7. Once the reading has stabilized and the display reads 'Ready', record the reading in a USP Laboratory Notebook.
8. Repeat above steps for all samples to be tested.
9. Remove probe, rinse with de-ionized water, and place the probe back into storage solution.

The pH of magnesium sulfate heptahydrate should be between 5.0 and 9.2 in a 1:20 solution.

7.0 Reference Documents

USP pH Meter Calibration and Maintenance (L12-PR-100-015)

8.0 Change Information

Updated SOP to current Doc System format
Removed Calibration and Maintenance sections
Added reference to *USP pH Meter Calibration and Maintenance (L12-PR-100-015)*