## 1.0 Purpose

The purpose of this procedure is to describe how to appropriately identify, collect, label, and store reserve samples that are representative of final repackaged product from each Lot. Retention of reserve samples is for the purpose of potential future evaluation of the quality of a Lot and not for future stability testing purposes.

## 2.0 Scope

This procedure applies to daily reserve samples of repackaged magnesium sulfate heptahydrate at the Repackaging facility.

## 3.0 Responsibility

Quality Associate – is responsible for following this procedure.

## 4.0 Safety Considerations

PPE required at Repackaging includes steel-toed shoes, safety glasses, hair/beard nets and smock.

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

- Giles Repackaging Daily Lot Change Label
- smudge/water-proof pen

## 6.0 Procedure

Reserve samples are only required (21 CFR 211.170) to be collected and retained for final repackaged USP product from each Lot. However, reserve samples are also collected daily for final repackaged Tech (fragrance) product from each Lot for the purpose of monitoring any physical characteristic changes such as color, fragrance distribution, or packaging integrity.

**Collection:**

- USP reserve samples are collected for each Lot (daily). These reserve samples are collected in the middle of the day and consist of each representative packaging (pouch, carton, etc.). This sample serves as the 'middle of a Lot' sample required for the beginning-middle-end USP sampling strategy.

- Tech (fragrance) reserve samples are also collected for each Lot (daily). These reserve samples consist of each representative packaging (pouch, carton, etc.).

- Obtain a Giles Repackaging Daily Lot Change Label and a smudge/water-proof pen. Clearly record required information on the label and place label on each reserve sample.

- Sufficient quantities of each type of reserve sample should be retained to conduct at least two full compendial analyses or, when the pharmacopoeial monograph is not applicable, twice the quantity necessary to perform any other required tests. A reserve sample should consist of a minimum of 1 pound.

**Documentation:**

- Record collection information for Tech (fragrance) reserve samples onto the *Daily Scented Reserve Sample Log (R12-PR-100-F008).*

- QA will log collection information from the USP reserve samples in the Manufacturing & Repackaging USP Test Samples & Retains Notebook.

- *Daily Scented Reserve Sample Log* or any other supporting documentation is filed in the Repackaging QA Lab for a period of at least one year.

- *Daily Reserve Sample Log* or any other supporting documentation is filed in the cGMP Library for a period of at least 4 years.

**Retention Location:**

- Place USP reserve samples with the USP Lot samples in designated area to be picked up and taken to the main QA Lab.

- USP reserve samples shall be retained and stored in the QA storage area as space permits and then transferred to an off-site storage facility for the remainder of the appropriate retention time.

- Tech (fragrance) reserve samples shall be retained and stored in the Repackaging QA Lab as space permits and then transferred to an off-site storage facility for the remainder of the appropriate retention time.

- These storage conditions are consistent with product labeling.

**Retention Time:**

- USP reserve samples representative of final repackaged product from each Lot are retained for at least one year after the expiry date of the specific Lot or for 4 years.

- Tech (fragrance) reserve samples representative of final repackaged scented product are retained for one year from the collection date of the sample.

## 7.0 Reference Documents

*Daily Scented Reserve Sample Log* *(R12-PR-100-F008)*

## 8.0 Change Information

Updated sample collection procedure to coincide with new daily final packaging testing protocol.
Changed reference to retention time of 1 year to 4 years for regulatory compliance.
Updated using new procedure template and numbering system.