**Purpose:**

The purpose of this document is to describe in detail the procedure for the retention of representative samples of USP/Tech grade magnesium sulfate heptahydrate.

**Scope:**

The scope of this document includes the packaging and holding of retained samples for the purpose of potential future evaluation of the finished product and not for future stability testing purposes.

**Procedure:**

1. Each lot of product will have a corresponding sample taken by a quality analyst for compendial analysis and retention at the facility. A sufficient quantity shall be obtained for at least three compendial analyses.
2. After laboratory testing, the retained sample shall be stored in the same, an equivalent, or a more protective packaging system than that in which the product is stored and marketed.
3. The sample packaging for each retained sample shall be labeled with lot number, date sampled and the initials of the quality analyst who obtained the sample.

1. Store samples at room temperature in the designated samples area.
2. Reserved samples of each lot shall be retained for one year after the expiry date of the lot.

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| Revision  Number | Revision  Date | Effective  Date | Revision  Author | Quality  Approval | Production Approval | Revision Description |
| 00 | 08/14/2012 | 08/14/2012 | Stephen Ballew | Deborah  Durbin | Jason  Bumgarner | New Document |
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