**Personnel responsible:**

All Production Employees

**Purpose or Objective:**

Proper handling of returned or rejected Epsom Salt

1. Referencing 21 CFR – Parts 210 & 211 - 211.204 – Returned drug products.

**Procedure:**

1. Returned or rejected Epsom Salt shall be identified and held as such.
2. If the conditions under which this product has been held, stored, or shipped before or during their return, or if the condition of the product, its container, carton, or labeling, as a result of storage or shipping, casts doubt on the identity, quality or purity of the product, the returned product shall be destroyed unless examination, testing, or other investigations prove product meets appropriate standards of identity, strength, quality, or purity.
3. Epsom salt may be reprocessed provided the subsequent product meets appropriate standards, specifications, and characteristics.
4. Records of returned product shall be maintained and shall include the reason for the return, quantity returned, date of disposition, and ultimate disposition of the returned product using form QA-17-F02
5. If the reason for a product being returned implicates associated batches, an appropriate investigation shall be conducted using QA-07-F02.
6. Procedures for the holding, testing, and reprocessing of returned product shall be in writing and shall be followed.

**Forms:**

QA-017-F02 – Non-Conforming Material Release

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| Revision  Number | Revision  Date | Effective  Date | Revision  Author | Quality  Approval | Production Approval | Revision Description |
| 00 | 08/21/12 | 08/21/12 | JB |  | JB | New Document |
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