1.0 Purpose

1.1 To ensure proper handling of returned or rejected Epsom Salt at Giles Chemical.
1.2 Referencing 21 CFR – Parts 210 & 211 - 211.204 – Returned drug products.

2.0 Scope

2.1 This applies to returned or rejected product.

3.0 Responsibility

3.1 Production Manager is responsible for this procedure

4.0 Safety Considerations

4.1 Special safety considerations are not applicable. 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

5.1 N/A

6.0 Procedure

6.1 Returned or rejected Epsom Salt shall be identified and held as such.

6.2 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.

6.3 Epsom salt may be reprocessed provided the subsequent product meets appropriate standards, specifications, and characteristics.

6.4 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 *Non-Conforming Material Release* Q12-FM-100-001.

6.5 If the reason for a product being returned implicates associated batches, an appropriate investigation shall be conducted using *Non-Conforming Material Release* Q12-FM-100-001.

6.6 Procedures for the holding, testing, and reprocessing of returned product shall be in writing and shall be followed.

7.0 Reference Documents

7.1 *Non-Conforming Material Release* Q12-FM-100-001

8.0 Amendment Record

Revision Number	Revision Date	Revision Author	Revision Description
0	08/21/12	JB	New Document