

## ELEMENTAL IMPURITY STATEMENT

Sodium Chloride Bio Excipient

NC3150

BioSpectra does not intentionally add any of the elements listed in ICH Q3D, USP <232>, and USP <233> to the BioSpectra manufacturing process of Sodium Chloride, Bio Excipient Grade product code NC3150. BioSpectra has evaluated the Raw Material Supply through the Supplier Approval Program and can state that raw materials are not expected to contain elemental impurities based on this evaluation. BioSpectra does not routinely analyze Sodium Chloride, Bio Excipient Grade product code NC3150 for elemental impurities.

For further information, please contact [info@biospectra.us](mailto:info@biospectra.us)



**Cassie Baun**  
Compliance Specialist