

ELEMENTAL IMPURITY STATEMENT

Sodium Chloride 5M Solution

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 5M Solution, Bio Excipient Grade. 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 5M Solution, Bio Excipient Grade for elemental impurities.

Current Product Number	Historic Product Number
NACL-3150	NC3150

For further information, please contact info@biospectra.us

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