

SODIUM CHLORIDE (5M) SOLUTION

UBLE, GMP, Excipient

CAS #: 7647-14-5

Formula: NaCl

F.W.: 58.44 g/mol

NACL-3150**Bio EXCIPIENT GRADE**

ANALYSIS	SPECIFICATIONS	
Appearance and Color	Clear Colorless Solution	
Molarity	4.9 – 5.1 M	
Endotoxin	< = 2.5 EU/mL	
Identification	Chloride Sodium	Passes Test Passes Test
Microbial Content	TAMC TYMC	< = 50 CFU/g < = 150 CFU/g
Trace Metals	Arsenic (As) Copper (Cu) Iron (Fe) Lead (Pb)	< = 2 ppm < = 2 ppm < = 2 ppm < = 2 ppm

General Product Overview

BioSpectra's Sodium Chloride 5M Solution meets stringent quality attributes for in-process and downstream use in BioPharma applications. The product is made with multicompendial salt and water for injection. It is sterile filtered into single use biocompatible packaging. This product and process is fully validated under FDA guidelines.

Click here to view SDS, CoAs and other supporting regulatory documents on our website.

Industry Application

Suitable for use as a cGMP chemical in pharmaceutical manufacturing processes and products.

Key Product Features

- The manufacturing of Sodium Chloride 5M Solution is performed at BioSpectra's Bangor, PA facility.
- Appears as a clear colorless solution
- Manufactured in accordance with ICH Q7
- Manufactured in an enzyme free, hormone free and animal free environment
- Contains no known major food allergens (as defined by FDA and WHO)
- The final product and its raw materials are not derived from nor come into contact with animal parts, animal products, and/or animal byproducts or derivatives.
- Is not subject to genetic modification

Storage and Shipping Conditions

Refer to SDS.

Standard Shelf-Life Policy

Unless otherwise noted on the Shelf-Life Statement and CoA, this product has a 2-year retest date supported by a 3-year ICH Q1 Stability Study (if one is completed).

Package Sizes

1,000L IBC – Sterile, Single-Use Container
200L Drum – Sterile, Single-Use Container

Made with WFI & Multicompendial NaCl xtl, Sterile Filtered into Sterile, Single Use Packaging.

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