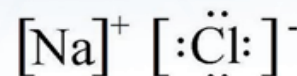


# Sodium Chloride 5M Soln., GMP, LBLE, Excipient Grade

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

### INTENDED FOR USE AS A GMP SOLUTION FOR CRITICAL PROCESS AND EXCIPIENT APPLICATIONS

BioSpectra's 5M GMP NaCl is manufactured under ISO Class 6 environmental controls to meet 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 custom, sterile, single use biocompatible packaging. This product and process is fully validated under FDA guidelines.



**Formula:** NaCl

**CAS #:** 7647-14-5

**Solubility in Water (g/L):**

360 g/L (25 °C)

**F.W.:** 58.44 g/mol

## EXCIPIENT GRADE | Product Code: NACL-3150 | Previously: NC3150

NaCl • F.W. 58.44 g/mol. • CAS# 7647-14-5



These are general specifications. BioSpectra will customize our products to meet your quality-based requirements.

ANALYSIS	SPECIFICATIONS
Appearance and Color	Clear Colorless Solution
Assay	4.9-5.1M
Endotoxin	≤ 2.5 EU/mL
<b>Identification</b>	
Chloride USP <191>	Meets Requirements
Sodium USP <191>	Meets Requirements
<b>Microbial Content</b>	
TAMC	≤ 50 CFU/g
TYMC	≤ 150 CFU/g
<b>Trace Metals</b>	
Arsenic (As)	≤ 2 ppm
Copper (Cu)	≤ 2 ppm
Iron (Fe)	≤ 2 ppm
Lead (Pb)	≤ 2 ppm



**Lead Time: 3-months**

**Minimum Order Quantity: For 1025L Tote: 4000-liters**

**For 200L Drum: 800-liters**

 Key Compliance Attributes of BioSpectra Grades	Bio Excipient Grade ICH-Q7 Compliant Manufactured
Suitable for Research and Diagnostic	✓
Each Batch 100% Analyzed	✓
Management of Change	✓
Validated Analytical Methods	✓
Compendial Testing	✓
Trace Metals Analyzed	✓
Stability Testing Program	✓
BioSpectra Supply Chain Audit Trail	✓
Product Origin Statement	✓
Customer Quality Audits	✓
Validated Manufacturing Process	✓
US Manufactured at BioSpectra	✓
IPEC cGMP Compliant Manufactured	✓
Customized Additional Specifications	✓
Multi-Compendial Testing	✓
Low Bioburden Low Endotoxin (LBLE)	✓
Enzyme Tested	✓
Suitable for use as Excipient	✓
Microbial / Endotoxin Tested	✓
Manufactured in FDA Registered Facility	✓
Customized Manufacturing Schedule	✓
Custom Regulatory Packet	✓
Accelerated Stability	✓
Video Conference access to BioSpectra Sites	✓
Complete access to Product Traceability	✓
Access to Supply Chain Information	✓
ICH-Q7 Qualified Utilities	✓
ICH-Q7 Compliant Manufactured	✓
Type IV Drug Master File	✓

## General Product Description:

The manufacturing of Bio Excipient Grade Sodium Chloride 5M, NACL-3150 is performed at BioSpectra's Bangor, PA facility and is conducted in a dedicated processing area using only dedicated equipment.

- Molecular Formula: NaCl
- Molecular Weight: 58.44 g/mol.
- CAS#: 7647-14-5
- Sodium Chloride 5M is a clear colorless solution.
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all Sodium Chloride 5M, NACL-3150 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products and/or byproducts.
- Sodium Chloride 5M solution manufactured at BioSpectra and any raw materials used in the manufacture of Sodium Chloride 5M at BioSpectra are not subject to genetic modification.
- Manufactured with WFI water.

## Storage and Shipping Conditions:

Ship and Store in ambient temperature.

## Package Sizes:

1025L in a BPC bag placed in a tote



✓ indicates an attribute or level of compliance which is granted or available based on the purchase of the product grade.

**Bio Excipient Grade:** Intended for use as ICH-Q7 Compliant Excipient

**LBLE:** LBLE applies when product specifications include requirements for Bioburden Testing (TAMC/TYMC and/or Endotoxin).

LBLE stands for Low Bioburden, Low Endotoxin non-sterile products suitable for further use in parenteral manufacturing and other sterile applications.

## GMP Compliance:

Bio Excipient Grade Sodium Chloride 5M NACL-3150 is suitable for use as an excipient. It is manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of Sodium Chloride 5M Solution is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.