

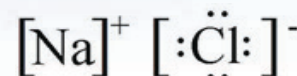
GMP Sodium Chloride 5M Solution

TECHNICAL
PRODUCT SHEET

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

**Sterile Filtered, Multicompendial Salt,
WFI, Sterile Single Use Package**

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 / 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
Identification	
Chloride USP <191>	Meets Requirements
Sodium USP <191>	Meets Requirements
Microbial Content	
TAMC	≤ 50 CFU/g
TYMC	≤ 150 CFU/g
Trace Metals	
Arsenic (As)	≤ 2 ppm
Copper (Cu)	≤ 2 ppm
Iron (Fe)	≤ 2 ppm
Lead (Pb)	≤ 2 ppm



 Key Compliance Attributes of BioSpectra Grades	Bio Excipient Grade ICH Q7 Compliant Manufactured
Suitable for Research and Diagnostic	Yes
Each Batch 100% Analyzed	Yes
Management of Change	Yes
Validated Analytical Methods	Yes
Compendial Testing	Yes
Trace Metals Analyzed	Yes
Stability Testing Program	Yes
BioSpectra Supply Chain Audit Trail	Yes
Product Origin Statement	Yes
Customer Quality Audits	Yes
Validated Manufacturing Process	Yes
US Manufactured at BioSpectra	Yes
IPEC cGMP Compliant Manufactured	Yes
Customized Additional Specifications	Yes
Multi-Compendial Testing	Available
Enzyme Tested	Available
Suitable for use as Excipient	Yes
Microbial / Endotoxin Tested	Yes
Manufactured in FDA Registered Facility	Yes
Customized Manufacturing Schedule	Available
Custom Regulatory Packet	Yes
Accelerated Stability	Available
Type IV Drug Master File	Available
Video Conference access to BioSpectra Sites	Available
Complete access to Product Traceability	Available
Access to Supply Chain Information	Yes
ICH Q7 Qualified Utilities	Yes
ICH Q7 Compliant Manufactured	Yes
Suitable for use as Active Ingredient	No
Type II Drug Master File	No

GMP Compliance:

Bio Excipient Grade Sodium Chloride 5M solution, NC3150 is suitable for use as an excipient. It is manufactured in accordance with the ICH Q7 Good Manufacturing Practice Guide. Bio Excipient Grade Sodium Chloride 5M solution, NC3150 is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

Storage and Shipping Conditions:

Ship and Store in ambient temperature.

General Product Description:

The manufacturing of Bio Excipient Grade Sodium Chloride 5M, NC3150 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, NC3150 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.

Package Sizes:

1025L in a BPC bag placed in a tote

