

Sodium Hydroxide (10N) Solution, Low Chloride, Low Carbonate, GMP Grade Low Iron, Made with WFI, BET Tested, GMP Manufactured

INTENDED FOR USE IN PHARMACEUTICAL GMP PROCESSES

High Purity Sodium Hydroxide 10N solution is intended for use in critical pharmaceutical processes, both upstream and downstream. This product is manufactured utilizing a proprietary, fully dedicated, validated GMP system that utilizes multiple manufacturing and purification steps to achieve high purity results without the use of pellets.

Lead Time: 1-2 Months

Minimum Order Quantity: 1000-liters



Formula: NaOH

F.W.: 40.00 g/mol

Density: 1.33 g/cm³ @ 20°C

Storage Temp: Ambient

CAS #: 1310-73-2

EC#: 215-185-5

UN: UN1824

ADR: 8,II, **Merck Index:** 14,08627

BIO PHARMA GRADE | Product Code: NAHY-4155 | Previously: NH4155

NaOH • F.W. 40 g/mol • CAS# 1310-73-2



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


ANALYSIS	SPECIFICATIONS
Appearance and Color	Clear / Colorless Liquid
Chloride	≤ 5 ppm
Endotoxins	≤ 2.0 EU/mL
Heavy Metals (as Pb)	≤ 1 ppm
Iron	≤ 2 ppm
Normality	9.9N – 10.1N
Sodium Carbonate	≤ 0.2%

General Product Description:

The manufacturing of Low Carbonate Bio Pharma Grade Sodium Hydroxide, NAHY-4155 is performed at BioSpectra's Bangor, PA, US FDA registered, GMP facility and is conducted in a dedicated processing area using only dedicated equipment.

- Molecular Formula: NaOH • Molecular Weight: 40.00 g/mol • CAS #: 1310-73-2
- Sodium Hydroxide 10N solution is a clear, colorless liquid.
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.
- BioSpectra certifies that all Sodium Hydroxide 10N solution, NAHY-4155 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products and/or byproducts.
- Sodium Hydroxide 10N solution manufactured at BioSpectra and any raw materials used in the manufacture of Sodium Hydroxide 10N solution at BioSpectra are not subject to genetic modification.



 Key Compliance Attributes of BioSpectra Grades	Bio Pharma Grade IPEC cGMP 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	✓

✓ indicates an attribute or level of compliance which is granted or available based on the purchase of the product grade.
Bio Pharma Grade: Intended for use as IPEC cGMP Compliant Chemical
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.

Package Sizes:

940L totes, 200L drums, 19L pails, 10L pails, 4x4L case and 6x1L case.

GMP Compliance:

Bio Pharma Grade Sodium Hydroxide NAHY-4155 is suitable for use as a process chemical. It is manufactured in accordance with the IPEC-PQG Joint Good Manufacturing Practice Guide. This grade of Sodium Hydroxide Solution is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

Retest Date:

BioSpectra can state that Sodium Hydroxide 10N Solution, Bio Pharma Grade manufactured at BioSpectra has undergone a 36-month stability testing program. A 24-month retest date is currently assigned based on the Long-Term Stability Data.

Storage and Shipping Conditions:

Ship and Store in ambient temperature, there is no impact to the product within ambient conditions of 10-40°C. Store in a clean and dry area. Store in the original container.

Material will freeze at slightly lower temperatures. Keep above 16°C to prevent freezing. Warming the product will allow for full dissolution of material.



GHS Classification:

Pictograms

Signal Word: **Danger**

Hazard Statements

H290 - May be corrosive to metals.

H314 - Causes severe skin burns and eye damage.

H318 - Causes serious eye damage.

H402 - Harmful to aquatic life.

Stability and Reactivity:

Chemical Stability: Stable.

Possibility of Hazardous Reactions: Will not occur.

Incompatible Materials: Acids, organic materials, chlorinated solvents, aluminum, phosphorus, zinc, tin.

Hazardous Decomposition Products: Sodium oxides.

Physical and Chemical Properties:

Appearance: Colorless liquid.

Odor: Odorless.

Odor threshold: Not Available.

pH: ~14

Boiling range: 105°C to 140°C

Flash Point: Not flammable.

Density: 1.33 g/cm³ @ 20°C

Solubility: Soluble in water.