

# Sodium Hydroxide (10N) Solution, Low Chloride, GMP Grade

Low Iron, Made with WFI, BET Tested, GMP Manufactured

### INTENDED FOR USE IN PHARMACEUTICAL GMP PROCESSES

High Purity Sodium Hydroxide 10N is intended for use in critical pharmaceutical processes both upstream and downstream. This product is manufactured utilizing a proprietary, 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 g/mol

**Density:** 1.32-1.34 g/cm<sup>3</sup> @ 20°C

**Storage Temp:** Ambient

**CAS #:** 1310-73-2

**EC#:** 215-185-5

**UN:** 1824 **ADR:** 8,II

**Merck Index:** 14,08627

**BIO PHARMA GRADE | Product Code: NAHY-4150** | Previously: NH4150

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	≤ 0.6%

### General Product Description:

The manufacturing of Bio Pharma Grade Sodium Hydroxide NAHY-4150 is performed at BioSpectra's Bangor, PA, USA 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 is a Clear / Colorless Liquid
- BioSpectra certifies that all Sodium Hydroxide NAHY-4150 at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products and/or byproducts.
- Sodium Hydroxide manufactured at BioSpectra and any raw materials used in the manufacture of Sodium Hydroxide at BioSpectra are not subject to genetic modification.
- Synonyms: NaOH Solution 10N, Sodium Hydroxide Solution 10N, Sodium Hydroxide 30% Solution, Sodium Hydrate



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

<p>✓ indicates an attribute or level of compliance which is granted or available based on the purchase of the product grade.</p> <p><b>Bio Pharma Grade:</b> Intended for use as IPEC cGMP Compliant Chemical</p> <p><b>LBLE:</b> 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.</p>
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## Package Sizes:

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

## GMP Compliance:

Bio Pharma Grade Sodium Hydroxide NAHY-4150 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. A 36-month expiry date may also be assigned for NAHY-4150 upon request.

## 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.** 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 (physical state, color, etc.) Colorless liquid.

Odor Odorless.

Odor threshold Not Available

pH ~14

Melting point/freezing point -12-10°C (10-50°F)

Initial boiling point and boiling range 105-140°C (221-284°F)

Flash point: Not Flammable.

Vapor density 1.33 (air=1)

Density 1.54 g/cm<sup>3</sup>

Solubility(ies) Soluble in water.