

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, 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 g/mol

Density: 1.32-1.34 g/cm³ @ 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 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	✓

<p>✓ indicates an attribute or level of compliance which is granted or available based on the purchase of the product grade.</p> <p>Bio Pharma Grade: Intended for use as IPEC cGMP Compliant Chemical</p> <p>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.</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/cm³

Solubility(ies) Soluble in water.