

# Sodium Hydroxide 8N (25%) Solution, GMP Grade

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

### INTENDED FOR USE IN PHARMACEUTICAL GMP PROCESSES

High Purity Sodium Hydroxide 8N 25% 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:** 1.280 g/cm<sup>3</sup> @ 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-4151 | Previously: NH4151**

NaOH • F.W. 40.00 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
Assay (NaOH)	24.5 – 25.5%
Chloride (Cl)	≤ 5 ppm
Endotoxin	≤ 2.0 EU/mL
Heavy Metals (as Pb)	≤ 1 ppm
Iron (Fe)	≤ 0.500 ppm

### General Product Description:

The manufacturing of Bio Pharma Grade Sodium Hydroxide 8N NAHY-4151 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 8N 25% 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 8N 25% solution, NAHY-4151 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products and/or byproducts.
- Sodium Hydroxide 8N 25% solution manufactured at BioSpectra and any raw materials used in the manufacture of Sodium Hydroxide 8N 25% solution at BioSpectra are not subject to genetic modification.



 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	✓

✓ 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.

## GMP Compliance:

Bio Pharma Grade Sodium Hydroxide 8N 25%, NAHY-4151 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 8N 25% Solution is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

## Retest Date:

The recommended retest period for Sodium Hydroxide 8N 25% solution is two years from the date of manufacture.

## 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:

Hazard Pictogram



Signal Word: **Danger**

Hazard Statements (GHS & CLP)

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: 112°C to 140°C

Flash Point: Not flammable.

Density: 1.280 g/cm<sup>3</sup> at 20°C

Solubility: Soluble in water.

## Package Sizes:

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