BIOSPECTRA
Premium Pharmaceutical Ingredients

GMP Solution
GMP Manufactured Process Chemical

Sodium Hydroxide (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 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

Na^+OH^-

Formula: NaOH
F.W.: 40.00 g/mol
Density: 1.280 g/cm^3 @ 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

Made in the USA

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 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 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 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 25% solution manufactured at BioSpectra and any raw materials used in the manufacture of Sodium Hydroxide 25% solution at BioSpectra are not subject to genetic modification.

BIOSPECTRA 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 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 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 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^3 at 20°C
Solubility: Soluble in water.

Package Sizes:

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