BIOSPECTRA
Premium Pharmaceutical Ingredients

GMP Solution
ICH-Q7 GMP Manufactured Product

Sodium Hydroxide (1N) Solution, GMP, Excipient Grade

Low Chloride, Low Iron, BET tested, Made with WFI, Sterile Filtered into Sterile Single Use Pkg.

INTENDED FOR USE IN PHARMACEUTICAL GMP PROCESSES

High Purity Sodium Hydroxide 1.0N 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: 3-months with SSU-Bag Inventory
6-months without SSU-Bag inventory

Minimum Order Quantity: 800-liters

Na^+OH^-

Formula: NaOH
F.W.: 40.00 g/mol
Density: 1.020 g/cm^3 at 20°C
Storage Temp: Ambient
CAS #: 1310-73-2
EC#: 215-185-5
UN: UN1824 **ADR:** 8,II
Merck Index: 14,08627

BIO EXCIPIENT GRADE | Product Code: NAHY-3153 | Previously: NH3153

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
Chloride	≤ 5 ppm
Endotoxins	≤ 2.0 EU/mL
Heavy Metals (as Pb)	≤1 ppm
Iron (Fe)	≤ 0.5 ppm
Normality	0.9N – 1.1N
Sterile Filtered	StyLux ST 0.2 Ultra Cap HD Filter from Meissner
Sterile Filtered in Sterile BPC	Verified

General Product Description:

The manufacturing of Bio Excipient Grade Sodium Hydroxide NAHY-3153 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 1N 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 1N solution, NAHY-3153 manufactured at BioSpectra and its raw materials are not derived from or come in contact with animal parts, products and/or byproducts.
- Sodium Hydroxide 1N solution manufactured at BioSpectra and any raw materials used in the manufacture of Sodium Hydroxide 1N solution at BioSpectra are not subject to genetic modification.

BioSpectra, Inc. 100 Majestic Way Bangor, PA 18013 610-599-3400

BIOSPECTRA Key Compliance Attributes of BioSpectra Grades	Bio Excipient Grade ICH-Q7 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	✓
ICH-Q7 Qualified Utilities	✓
ICH-Q7 Compliant Manufactured	✓
Type IV Drug Master File	✓

✓ indicates an attribute or level of compliance which is granted or available based on the purchase of the product grade.

Bio Excipient Grade: Intended for use as ICH-Q7 Compliant Excipient

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 Excipient Grade Sodium Hydroxide Solution 1N, NAHY-3153 is suitable for use as an excipient. It is manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of Sodium Hydroxide Solution 1N is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

Retest Date:

The recommended retest period for Sodium Hydroxide 1N 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 (GHS & CLP)

Signal Word (GHS & CLP): **Danger**

Hazard Statements (GHS & CLP)

H290 May be corrosive to metals
H314 Causes severe skin burns and eye damage

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: 100°C to 140°C
Flash Point: Not flammable.
Density: 1.020 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.