GMP BIOTECH PRODUCT

SODIUM HYDROXIDE 10N SOLUTION

LOW CHLORIDE, GMP

CAS #: 1310-73-2 Formula: NaOH F.W.: 40.00 g/mol

NAHY-4126

BIO PHARMA GRADE

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Analysis			Specifications
Absorbanc	e (Neat)	260 nm 280 nm	< = 0.080 a.u. < = 0.050 a.u.
Appearance and Color			Clear, Colorless Solution
Chloride			< = 5 ppm
Endotoxin			< = 2.0 EU/mL
Enzymes		DNase RNase Protease	None Detected None Detected None Detected
Normality			9.9 – 10.1 N
Sodium Carbonate			< = 0.6%
Trace Metals	Bis Cadi Chro Chro Magne Manga Molybde	arium (Ba) smuth (Bi) lcium (Ca) mium (Cd) cobalt (Co) mium (Cr) opper (Cu) Iron (Fe) sium (Mg) nese (Mn) enum (Mo) Nickel (Ni) Lead (Pb) ntium (Sr) Zinc (Zn)	< = 1 ppm < = 1 ppm < = 5 ppm < = 1 ppm < = 1 ppm < = 1 ppm < = 2 ppm < = 1 ppm

Country of Origin: USA

Intended for Use in Biopharmaceutical & Biotechnological Applications and Products

Sodium Hydroxide 10N Solution is a high purity, GMP reagent grade product. This product is manufactured utilizing a proprietary, fully dedicated, validated cGMP system that utilizes multiple manufacturing and purification steps to achieve high purity results without the use of pellets.

General Product Description

- Appears as a clear, colorless solution
- Manufactured in accordance with IPEC
- Manufactured in an enzyme free, hormone free and animal free environment
- Contains no known major food allergens (as defined by FDA and WHO)
- The final product and its raw materials are not derived from nor come into contact with animal parts, animal products, and/or animal byproducts or derivatives.
- Is not subject to genetic modification
- Synonyms: NaOH Solution 10N, Sodium Hydroxide Solution 10N, Sodium Hydroxide 30% Solution
- Visit the product page on our website (<u>www.biospectra.us</u>) for additional information, supporting regulatory documents, and CoAs.

Storage and Shipping Conditions

Refer to SDS.

Standard Shelf Life Policy

Each Certificate of Analysis will contain a 2-year retest date supported by a 3-year ICH Q1 Stability Study (if one is completed).

Package Sizes

6x1L case, 4x1gal (3.78L each) case (15L total), 10L carboy, 200L poly drum, IBC's - custom filled: 940L, 1000L, 1100L

Standard Lead Time

2-4 weeks

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