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Sodium Hydroxide

NaOH 40.00
Sodium hydroxide CAS RN®: 1310-73-2.

DEFINITION

Sodium Hydroxide contains NLT 95.0% and NMT 100.5% of total alkali, calculated as sodium hydroxide (NaOH), including NMT 3.0% of sodium carbonate (Na_2CO_3). It also contains NLT 54.0% and NMT 59.8% of sodium.

[**Caution—**Exercise great care in handling sodium hydroxide, because it rapidly destroys tissues.]

IDENTIFICATION

- **A. Identification Tests—General ⟨191⟩, *Chemical Identification Tests, Sodium*:** A solution (1 in 25) meets the requirements.
- **B. pH ⟨791⟩**
  Sample solution: 0.1 mg/mL of Sodium Hydroxide
  Acceptance criteria: NLT 11.0

ASSAY

- **Total Alkali**
  Sample: 1.5 g
  Blank: 40.0 mL of carbon dioxide-free water
  Titrimetric system
  (See *Titrimetry* ⟨541⟩.)
  Mode: Direct titration
  Titrant: 1 N sulfuric acid VS
  Endpoint detection: Visual
  Analysis: Dissolve the *Sample* in 40 mL of carbon dioxide-free water. Cool the solution to room temperature, and add phenolphthalein TS. Titrate with 1 N sulfuric acid VS. At the discharge of the pink color of the indicator, record the volume of *Titrant* (V_{S1}). Add methyl orange TS, and continue the titration until a persistent pink color is produced. Record the volume of *Titrant* (V_{S2}). Perform a blank determination, and make any necessary corrections.
  Calculate the percentage of total alkali, calculated as sodium hydroxide (NaOH), in the *Sample* taken:

$$\text{Result} = \{[(V_{S2} - V_B) \times N \times F_1]/W\} \times 100$$

V_{S2} = volume of *Titrant* consumed by the *Sample* to the second endpoint (mL)

V_B = volume of *Titrant* consumed by the *Blank* (mL)

N = actual normality of the *Titrant* (mEq/mL)

F_1 = equivalency factor, 40.00 mg/mEq

W = weight of the *Sample* (mg)

Calculate the percentage of sodium carbonate (Na_2CO_3) in the *Sample* taken:

$$\text{Result} = \{[(V_{S2} - V_{S1}) \times N \times F_2]/W\} \times 100$$

V_{S2} = volume of *Titrant* consumed by the *Sample* to the second endpoint (mL)

V_{S1} = volume of *Titrant* consumed by the *Sample* to the first endpoint (mL)

N = actual normality of the *Titrant* (mEq/mL)

F_2 = equivalency factor, 106.0 mg/mEq

W = weight of the *Sample* (mg)

Acceptance criteria: 95.0%–100.5% of total alkali; NMT 3.0% of sodium carbonate (Na_2CO_3)

- **Content of Sodium**

Diluent: 1% hydrochloric acid solution

Standard stock solution: 25.41 µg/mL of sodium chloride in *Diluent*. This solution contains 10 µg/mL of sodium.

Standard solutions: Transfer 6.0-, 7.5-, and 9.0-mL portions of *Standard stock solution* to separate 100-mL volumetric flasks. Dilute the content of each flask with *Diluent* to volume, and mix to obtain solutions having known concentrations of 0.6, 0.75, and 0.9 µg/mL of sodium, respectively.

Sample stock solution: 1.303 mg/mL of Sodium Hydroxide in *Diluent*

Sample solution: Transfer 0.1 mL of *Sample stock solution* to a 100-mL volumetric flask and dilute with *Diluent* to volume.

Instrumental conditions

(See *Atomic Absorption Spectroscopy ⟨852⟩*.)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: 589.0 nm (sodium emission line)

Lamp: Sodium hollow-cathode

Flame: Air–acetylene

Blank: *Diluent*

Standard curve

Samples: *Standard solutions*

Plot: Absorbance values versus their corresponding concentration (µg/mL) of sodium. The correlation coefficient is NLT 0.995.

Analysis

Sample: *Sample solution*

From the *Standard curve*, determine the concentration of sodium in the *Sample solution*.

Calculate the percentage of sodium in the portion of Sodium Hydroxide taken:

$$\text{Result} = (C_S/C_U) \times 100$$

C_S = concentration of sodium in the *Sample solution* from the *Standard curve* (µg/mL)

C_U = concentration of Sodium Hydroxide in the *Sample solution* (µg/mL)

Acceptance criteria: 54.0%–59.8%

IMPURITIES

- **Potassium**

Diluent: 1% hydrochloric acid solution

Standard stock solution: 1.907 mg/mL of potassium chloride, previously dried at 105° for 2 h, in water. Transfer 5.0 mL of this solution to a 1.0-L volumetric flask and dilute with *Diluent* to volume. This solution contains 5 µg/mL of potassium.

Standard solutions: Transfer 2.0-, 5.0-, and 10.0-mL portions of the *Standard stock solution* to separate 100-mL volumetric flasks. Dilute the content of each flask with *Diluent* to volume, and mix to obtain solutions having known concentrations of 0.10, 0.25, and 0.50 µg/mL of potassium, respectively.

Sample stock solution: 0.5 mg/mL of Sodium Hydroxide

Sample solution: 50 µg/mL of Sodium Hydroxide in *Diluent*, prepared from the *Sample stock solution*

Instrumental conditions

(See *Atomic Absorption Spectroscopy ⟨852⟩*.)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: 766.5 nm (potassium emission line)

Lamp: Potassium hollow-cathode

Flame: Air–acetylene

Blank: *Diluent*

Standard curve

Samples: *Standard solutions*

Plot: Absorbance values versus their corresponding concentration (µg/mL) of potassium. The correlation coefficient is NLT 0.99.

Analysis

Sample: *Sample solution*

From the *Standard curve*, determine the concentration of potassium in the *Sample solution*.

Calculate the percentage of potassium in the portion of Sodium Hydroxide taken:

$$\text{Result} = (C_S/C_U) \times 100$$

C_S = concentration of potassium in the *Sample solution* from the *Standard curve* (µg/mL)

C_U = concentration of Sodium Hydroxide in the *Sample solution* (µg/mL)

Acceptance criteria: NMT 0.5%

SPECIFIC TESTS

• **Insoluble Substances and Organic Matter:** A solution (1 in 20) is complete, clear, and colorless to slightly colored.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
SODIUM HYDROXIDE	Documentary Standards Support	SE2020 Simple Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SE2020 Simple Excipients

Chromatographic Database Information: Chromatographic Database

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