

Status: Currently Official on 18-Feb-2025
 Official Date: Official as of 01-Jan-2018
 Document Type: NF Monographs
 DocId: GUID-AA7C755C-5EF7-418D-97A8-20E6A2A151FA_3_en-US
 DOI: https://doi.org/10.31003/USPNF_M67610_03_01
 DOI Ref: w52u9

© 2025 USPC
 Do not distribute

Potassium Hydroxide

KOH 56.11

Potassium hydroxide CAS RN®: 1310-58-3.

DEFINITION

Potassium Hydroxide contains NLT 85.0% of total alkali, calculated as potassium hydroxide (KOH), including NMT 3.5% of potassium carbonate (K_2CO_3). It also contains NLT 59.9% of potassium.

[CAUTION—Exercise great care in handling Potassium Hydroxide because it rapidly destroys tissues.]

IDENTIFICATION

• **A. IDENTIFICATION TESTS—GENERAL (191), Potassium:** A solution (1 in 25) meets the requirements.

• **B. pH (791).**

Sample solution: 0.1 mg/mL of Potassium Hydroxide

Acceptance criteria: NLT 10.5

ASSAY

• TOTAL ALKALI

Sample: 1.5 g of Potassium Hydroxide

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: [1 N sulfuric acid VS](#)

Endpoint detection: Colorimetric

Analysis: Dissolve the *Sample* in 40 mL of carbon dioxide-free water. Cool the solution to 15° 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 acid solution required, then add [methyl orange TS](#) and continue the titration to a persistent pink color. Each milliliter of 1 N sulfuric acid is equivalent to 56.11 mg of total alkali, calculated as potassium hydroxide (KOH), and each milliliter of acid consumed in the titration with methyl orange is equivalent to 138.2 mg of potassium carbonate (K_2CO_3).

Acceptance criteria: NLT 85.0% of total alkali, calculated as potassium hydroxide (KOH), including NMT 3.5% of potassium carbonate (K_2CO_3)

• CONTENT OF POTASSIUM

Diluent: 1% [hydrochloric acid](#) solution

Sodium chloride solution: 0.2 g/mL of [sodium chloride](#)

Blank solution: Transfer 2.0 mL of the *Sodium chloride solution* to a 100-mL volumetric flask and dilute with *Diluent* to volume.

Standard stock solution: 57.21 µg/mL of [potassium chloride](#), previously dried at 105° for 2 h, in water. This solution contains 30 µg/mL of potassium.

Standard solutions: Transfer 2.0-, 4.0-, and 6.0-mL portions of the *Standard stock solution* to separate 100-mL volumetric flasks. To each flask, add 2.0 mL of the *Sodium chloride solution*. Dilute the content of each flask with *Diluent* to volume and mix to obtain solutions with known concentrations of 0.6, 1.2, and 1.8 µg/mL of potassium.

Sample stock solution: 0.5 mg/mL of Potassium Hydroxide

Sample solution: Transfer 1.0 mL of the *Sample stock solution* to a 250-mL volumetric flask. Add 5.0 mL of the *Sodium chloride solution* and dilute with *Diluent* to volume.

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: *Blank solution*

Standard curve

Samples: *Standard solutions*

Plot: Absorbance values versus their corresponding concentrations (µg/mL) of potassium. The correlation coefficient is NLT 0.999.

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 Potassium 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 Potassium Hydroxide in the *Sample solution* (µg/mL)

Acceptance criteria: NLT 59.9%

IMPURITIES

• LIMIT OF SODIUM

Diluent: 1% [hydrochloric acid](#) solution

Standard stock solution: 12.71 µg/mL of [sodium chloride](#), previously dried at 105° for 2 h, in water. This solution contains 5 µg/mL of sodium.

Standard solutions: Transfer 1.0-, 10.0-, and 15.0-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 with known concentrations of 0.05, 0.5, and 0.75 µg/mL of sodium.

Sample stock solution: 0.5 mg/mL of Potassium Hydroxide

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

Instrumental conditions

(See [Atomic Absorption Spectroscopy \(852\)](#).)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: 589.0 nm

Lamp: Sodium hollow-cathode

Flame: Air–acetylene

Blank: *Diluent*

Standard curve

Samples: *Standard solutions*

Plot: Absorbance values versus their corresponding concentrations (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 Potassium 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 Potassium Hydroxide in the *Sample solution* (µg/mL)

Acceptance criteria: NMT 1.0%

SPECIFIC TESTS

• INSOLUBLE SUBSTANCES

Sample solution: 1 g of Potassium Hydroxide in 20 mL of water

Acceptance criteria: The *Sample solution* is complete, clear, and colorless.

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
POTASSIUM HYDROXIDE	Documentary Standards Support	SE2020 Simple Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SE2020 Simple Excipients

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. 48(6)

Current DocID: GUID-AA7C755C-5EF7-418D-97A8-20E6A2A151FA_3_en-US

Previous DocID: GUID-AA7C755C-5EF7-418D-97A8-20E6A2A151FA_1_en-US

DOI: https://doi.org/10.31003/USPNF_M67610_03_01

DOI ref: [w52u9](#)

OFFICIAL