

Status: Currently Official on 14-Feb-2025  
Official Date: Official as of 01-Jun-2023  
Document Type: USP Monographs  
DocId: GUID-E4A93B5E-8221-4346-B528-F651BF524992\_4\_en-US  
DOI: [https://doi.org/10.31003/USPNF\\_M11500\\_04\\_01](https://doi.org/10.31003/USPNF_M11500_04_01)  
DOI Ref: I4u0p

© 2025 USPC  
Do not distribute

# Calcium Chloride

$\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$  147.01  
Calcium chloride dihydrate CAS RN®: 10035-04-8.  
 $\text{CaCl}_2$  110.98  
Anhydrous CAS RN®: 10043-52-4.

## DEFINITION

Calcium Chloride contains an amount of  $\text{CaCl}_2$  equivalent to NLT 99.0% and NMT 107.0% of  $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$ .

## IDENTIFICATION

- **A. IDENTIFICATION TESTS—GENERAL, [Calcium](#) (191).**  
**Sample solution:** 100 mg/mL  
**Acceptance criteria:** Meets the requirements
- **B. IDENTIFICATION TESTS—GENERAL, [Chloride](#) (191).**  
**Sample solution:** 100 mg/mL  
**Acceptance criteria:** Meets the requirements

## ASSAY

- **PROCEDURE**  
**Sample solution:** Dissolve 1 g of Calcium Chloride in a mixture of water and 3 N hydrochloric acid (100:5). Transfer the solution to a 250-mL volumetric flask, and dilute with water to volume.  
**Analysis:** Pipet 50 mL of the *Sample solution* into a suitable container, and add 100 mL of water, 15 mL of 1 N sodium hydroxide, and 300 mg of hydroxy naphthol blue. Titrate with 0.05 M edetate disodium VS until the solution is deep blue. Each mL of 0.05 M edetate disodium is equivalent to 7.351 mg of calcium chloride dihydrate ( $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$ ).  
**Acceptance criteria:** 99.0%–107.0% of  $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$

## IMPURITIES

**Change to read:**

- ▲ [ALUMINUM \(206\), Procedure 1](#) ▲ (CN 1-JUN-2023)

[NOTE—Perform if labeled as intended for use in hemodialysis.]

**Test preparation:** Use a 2.0-g sample.  
**Acceptance criteria:** NMT 1 ppm

- **IRON, ALUMINUM, AND PHOSPHATE**

**Sample solution:** 50 mg/mL  
**Analysis:** Add 2 drops of 3 N hydrochloric acid and 1 drop of phenolphthalein TS to the *Sample solution*. Then add ammonium chloride–ammonium hydroxide TS, dropwise, until the solution is faintly pink. Add 2 drops in excess, and heat the liquid to boiling.  
**Acceptance criteria:** No turbidity or precipitate is produced.

- **LIMIT OF MAGNESIUM AND ALKALI SALTS**

**Sample solution:** 20 mg/mL  
**Analysis:** To 50 mL of *Sample solution* add 500 mg of ammonium chloride. Heat the solution, and boil for 1 min. Rapidly add 40 mL of oxalic acid TS, and stir vigorously until precipitation is well established. Add immediately to the warm mixture 2 drops of methyl red TS and then 6 N ammonium hydroxide, dropwise, until the mixture is just alkaline. Cool to room temperature. Transfer to a 100-mL graduated cylinder, dilute with water to 100 mL, mix, and allow to stand for 4 h or overnight. Filter, and to 50 mL of the clear filtrate in a platinum dish, add 0.5 mL of sulfuric acid, and evaporate the mixture on a steam bath to a small volume. Carefully heat over a free flame to dryness, and continue heating to complete decomposition and volatilization of ammonium salts. Finally, ignite the residue to constant weight.  
**Acceptance criteria:** The weight of the residue is NMT 5 mg (1.0%).

## SPECIFIC TESTS

- **[pH](#) (791).**  
**Sample solution:** 50 mg/mL  
**Acceptance criteria:** 4.5–9.2

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **LABELING:** Where Calcium Chloride is intended for use in hemodialysis, it is so labeled.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
CALCIUM CHLORIDE	<a href="#">Documentary Standards Support</a>	SM52020 Small Molecules 5

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 29(5)

Current DocID: GUID-E4A93B5E-8221-4346-B528-F651BF524992\_4\_en-US

DOI: [https://doi.org/10.31003/USPNF\\_M11500\\_04\\_01](https://doi.org/10.31003/USPNF_M11500_04_01)

DOI ref: [l4u0p](#)

OFFICIAL