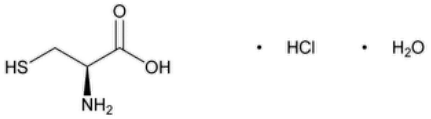
Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Jun-2023
Document Type: USP Monographs
DocId: GUID-748D6C1E-FC9E-440C-A348-0AA04655AD6C_5_en-US
DOI: https://doi.org/10.31003/USPNF_M21760_05_01
DOI Ref: n3679

Cysteine Hydrochloride



$C_3H_7NO_2S \cdot HCl \cdot H_2O$ 175.63
$C_3H_7NO_2S \cdot HCl$ 157.62

L-Cysteine hydrochloride monohydrate CAS RN®: 7048-04-6.
Anhydrous CAS RN®: 52-89-1; UNII: A9U1687S1S.

DEFINITION

Cysteine Hydrochloride is L-cysteine hydrochloride monohydrate and contains NLT 98.5% and NMT 101.5% of L-cysteine hydrochloride ($C_3H_7NO_2S \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**

ASSAY

• **Procedure**

Sample: 250 mg of Cysteine Hydrochloride

Blank: Proceed as directed in the *Analysis* without the *Sample*.

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: Residual titration

Titrant: 0.1 N iodine VS

Back-titrant: 0.1 N sodium thiosulfate VS

Endpoint detection: Visual

Analysis: Transfer the *Sample* to an iodine flask. Add 20.0 mL of water and 4 g of potassium iodide, and mix. Cool the solution in an ice bath, and add 5 mL of 3 N hydrochloric acid and 25.0 mL of 0.1 N iodine VS. Insert the stopper, and allow to stand in the dark for 20 min, while remaining in the ice bath. Titrate the excess iodine with the *Back titrant*. Add 3 mL of starch TS as the endpoint is approached. Perform the *Blank* determination.

Calculate the percentage of cysteine hydrochloride ($C_3H_7NO_2S \cdot HCl$) in the portion of Cysteine Hydrochloride taken:

$$\text{Result} = \{[(V_B - V_S) \times N \times F]/W\} \times 100$$

V_B = *Back-titrant* volume consumed by the *Blank* (mL)

V_S = *Back-titrant* volume consumed by the *Sample* (mL)

N = actual normality of the *Back-titrant* (mEq/mL)

F = equivalency factor, 157.6 mg/mEq

W = *Sample* weight (mg)

Acceptance criteria: 98.5%–101.5% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.4%

• **Chloride and Sulfate ⟨221⟩, *Sulfate***

Standard solution: 0.10 mL of 0.020 N sulfuric acid

Sample: 0.33 g of Cysteine Hydrochloride

Acceptance criteria: NMT 0.03%

Change to read:

• **▲Iron ⟨241⟩, *Procedures, Procedure 1*▲** (CN 1-Jun-2023) **:** NMT 30 ppm

• **Related Compounds**

***N*-Ethylmaleimide solution:** 40 mg/mL of N-ethylmaleimide in alcohol

Standard stock solution: Dissolve 20 mg of USP L-Cysteine Hydrochloride RS in 10.0 mL of water. Add 10.0 mL of *N-Ethylmaleimide solution*, and mix. Allow the solution to stand for 5 min before using.

Standard solution: 0.05 mg/mL from *Standard stock solution* in water. [Note—This solution has a concentration equivalent to 0.5% of that of the *Sample solution*.]

System suitability solution: Transfer 10 mg of USP L-Tyrosine RS and 10 mL of the *Standard stock solution* to a 25-mL volumetric flask. Dilute with water to volume.

Sample stock solution: Transfer 0.2 g of Cysteine Hydrochloride to a 10-mL volumetric flask. Dissolve and dilute with water to volume.

Sample solution: To 5.0 mL of the *Sample stock solution* add 5.0 mL of *N-Ethylmaleimide solution*, and mix. Allow the solution to stand for 5 min before using.

Chromatographic system

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 5 µL

Developing solvent system: Butyl alcohol, glacial acetic acid, and water (3:1:1)

Spray reagent: 2 mg/mL of ninhydrin in a mixture of butyl alcohol and 2 N acetic acid (95:5)

System suitability

Suitability requirements: The chromatogram of the *System suitability solution* exhibits two clearly separated spots.

Analysis

Samples: *Standard solution*, *System suitability solution*, and *Sample solution*

After air-drying the plate, spray with *Spray reagent*, and heat between 100° and 105° for 15 min. Examine the plate under white light.

Acceptance criteria: Any secondary spot of the *Sample solution* is not larger or more intense than the principal spot of the *Standard solution*.

Individual impurities: NMT 0.5%

Total impurities: NMT 2.0%

SPECIFIC TESTS

• **Optical Rotation ⟨781S⟩, *Procedures, Specific Rotation***

Sample solution: 80 mg/mL in 6 N hydrochloric acid

Acceptance criteria: +5.7° to +6.8°

• **Loss on Drying ⟨731⟩**

Analysis: Dry at room temperature for 24 h in a vacuum desiccator using a suitable desiccant and maintaining a pressure of NMT 5 mm of mercury (Hg).

Acceptance criteria: 8.0%–12.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **USP Reference Standards ⟨11⟩**

USP L-Cysteine Hydrochloride RS

USP L-Tyrosine RS

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

Topic/Question	Contact	Expert Committee
CYSTEINE HYDROCHLORIDE	Fatkhulla K Tadjimukhamedov Associate Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 42(1)

Current DocID: GUID-748D6C1E-FC9E-440C-A348-0AA04655AD6C_5_en-US

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