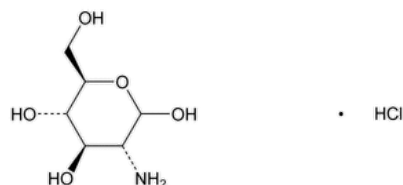


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Glucosamine Hydrochloride



$C_6H_{13}NO_5 \cdot HCl$ 215.63

D-Glucose, 2-amino-2-deoxy-, hydrochloride;

2-Amino-2-deoxy-β-D-glucopyranose hydrochloride CAS RN®: 66-84-2.

DEFINITION

Glucosamine Hydrochloride contains NLT 98.0% and NMT 102.0% of glucosamine hydrochloride ($C_6H_{13}NO_5 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), *Infrared Spectroscopy*:** 197K
- **B. IDENTIFICATION TESTS—GENERAL, *Chloride*(191):** Meets the requirements
- **C.** The retention time of the glucosamine peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Buffer: In a 1-L volumetric flask, dissolve 3.5 g of dibasic potassium phosphate in water. Add 0.25 mL of ammonium hydroxide, dilute with water to volume, and mix. Adjust with phosphoric acid to a pH of 7.5.

Mobile phase: Acetonitrile and *Buffer* (75:25)

Diluent: Acetonitrile and water (50:50)

Standard solution: 3.8 mg/mL of [USP Glucosamine Hydrochloride RS](#) in *Diluent*

Sample solution: 3.8 mg/mL of Glucosamine Hydrochloride in *Diluent*. [NOTE—Shake by mechanical means to aid dissolution.]

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 195 nm

Column: 4.6-mm × 15-cm; 5-μm packing L8

Column temperature: 35°

Flow rate: 1.5 mL/min

Injection size: 10 μL

System suitability

Sample: *Standard solution*

[NOTE—The peak for the glucosamine moiety elutes at about 10 min. The chromatogram shows a large additional peak near the void volume, due to the chloride ion.]

Suitability requirements

Tailing factor: NMT 2.0 for the glucosamine peak

Efficiency: NLT 1500 theoretical plates

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of glucosamine hydrochloride ($C_6H_{13}NO_5 \cdot HCl$) in the portion of Glucosamine Hydrochloride taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Glucosamine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Glucosamine Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%
- [CHLORIDE AND SULFATE, Sulfate \(221\)](#): A 0.10-g portion shows no more sulfate than corresponds to 0.25 mL of 0.020 N sulfuric acid (NMT 0.24%).

Change to read:

- [ARSENIC \(211\), Procedures, Procedure 2](#) ▲ (CN 1-JUN-2023) : NMT 3 ppm

SPECIFIC TESTS

- [OPTICAL ROTATION, Specific Rotation \(781S\)](#): +70.0° to +73.0°
Sample solution: 25 mg/mL. Measure the specific rotation 3 h after preparation.
- [pH \(791\)](#)
Sample solution: 20 mg/mL
Acceptance criteria: 3.0–5.0
- [LOSS ON DRYING \(731\)](#): Dry a sample at 105° for 2 h: it loses NMT 1.0% of its weight.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP Glucosamine Hydrochloride RS](#)

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

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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