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# Glucosamine Sulfate Sodium Chloride

$(C_6H_{14}NO_5)_2SO_4 \cdot 2NaCl$  573.31

Bis(D-glucose, 2-amino-2-deoxy-), sulfate sodium chloride complex;

Bis(2-amino-2-deoxy-β-D-glucopyranose) sulfate sodium chloride complex (-, -) CAS RN®: 1296149-13-7.

## DEFINITION

Glucosamine Sulfate Sodium Chloride contains NLT 98.0% and NMT 102.0% of glucosamine sulfate sodium chloride  $[(C_6H_{14}NO_5)_2SO_4 \cdot 2NaCl]$ , calculated on the dried basis.

## IDENTIFICATION

### • A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#)

**Sample:** Transfer 50 mg of Glucosamine Sulfate Sodium Chloride to a centrifuge tube, and dissolve in 2 mL of water. Add 0.5 mL of barium chloride TS, and centrifuge. Collect the supernatant, and evaporate to dryness. Dry the residue at 105° for 2 h.

**Acceptance criteria:** The IR spectrum of the *Sample* matches that of a similar preparation of [USP Glucosamine Hydrochloride RS](#), except that the addition of barium chloride TS is omitted.

### • B. [IDENTIFICATION TESTS—GENERAL, Chloride \(191\) and Sodium \(191\)](#): 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.

### • D. **SULFATE:** In the test for *Content of Sulfate*, after the addition of barium chloride TS a white precipitate is formed.

## 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*. Shake for 5 min by mechanical means to completely dissolve.

**Sample solution:** Transfer 250 mg of Glucosamine Sulfate Sodium Chloride to a 50-mL volumetric flask. Dissolve in 30 mL of *Diluent*, and shake by mechanical means. Dilute with *Diluent* to volume.

### 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 additional peaks near the void volume, due to the counter ions.]

### 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 sulfate sodium chloride  $[(C_6H_{14}NO_5)_2SO_4 \cdot 2NaCl]$  in the portion of Glucosamine Sulfate Sodium Chloride taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

$r_U$  = 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 Sulfate Sodium Chloride in the *Sample solution* (mg/mL)

$M_{r1}$  = molecular weight of glucosamine sulfate sodium chloride, 573.31

$M_{r2}$  = twice the molecular weight of glucosamine hydrochloride, 431.26

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

**OTHER COMPONENTS****• CONTENT OF SULFATE**

**Sample:** 1 g of Glucosamine Sulfate Sodium Chloride

**Analysis:** Transfer the *Sample* to a 250-mL beaker, and dissolve in 100 mL of water. Add 4 mL of 6 N hydrochloric acid. Heat the solution to boiling, and add, with constant stirring, sufficient boiling barium chloride TS to completely precipitate the sulfate. Add an additional 2 mL of barium chloride TS, and digest on a steam bath for 1 h. Pass the mixture through ashless filter paper. Transfer the residue quantitatively to a new filter, and wash the residue with hot water until no precipitate is obtained when 1 mL of silver nitrate TS is added to 5 mL of washing. Transfer the paper containing the residue to a tared crucible. Char the paper, without burning, and ignite the crucible and its contents to constant weight. Calculate the content of sulfate by multiplying the weight obtained by 0.4116.

**Acceptance criteria:** 16.3%–17.3%

**IMPURITIES**

- [RESIDUE ON IGNITION \(281\)](#): 22.5%–26.0%

**Change to read:**

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

**• POTASSIUM**

**Analysis:** Acidify 5 mL of a solution (1 in 20) with 6 N acetic acid, and add 5 drops of sodium cobaltinitrite TS.

**Acceptance criteria:** No precipitate is formed.

**SPECIFIC TESTS**

- [OPTICAL ROTATION, Specific Rotation \(781S\)](#)

**Sample solution:** 35 mg/mL. Measure the specific rotation 3 h after preparation.

**Acceptance criteria:** +50.0° to +55.0°

- [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                                                                                                                   |
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