

Status: Currently Official on 15-Feb-2025
 Official Date: Official Prior to 2013
 Document Type: Dietary Supplement Monographs
 DocId: GUID-A3E68E1D-657C-472A-960A-8BFA21618334_1_en-US
 DOI: https://doi.org/10.31003/USPNF_M35205_01_01
 DOI Ref: h8vwd

© 2025 USPC
 Do not distribute

Glucosamine Tablets

DEFINITION

Glucosamine Tablets are prepared from Glucosamine Hydrochloride, Glucosamine Sulfate Sodium Chloride, Glucosamine Sulfate Potassium Chloride, or a mixture of any of them. Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of glucosamine ($C_6H_{13}NO_5$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the test for *Content of Glucosamine*.
- **B.** [IDENTIFICATION TESTS—GENERAL, Chloride\(191\)](#): Meets the requirements
- **C.** [IDENTIFICATION TESTS—GENERAL, Sulfate\(191\)](#): Meets the requirements. [NOTE—Only for Tablets labeled as containing glucosamine sodium sulfate or glucosamine potassium sulfate]

STRENGTH

• CONTENT OF GLUCOSAMINE

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

Sample solution: Weigh and finely powder NLT 20 Tablets. Transfer an accurately weighed portion of the finely powdered material, equivalent to about 312 mg of glucosamine, to a 100-mL volumetric flask. Add 60 mL of *Diluent*, and sonicate for 10 min. Shake by mechanical means for 15 min. Dilute with *Diluent* to volume, and mix. Pass a portion of this solution through a membrane filter of 0.45- μ m or finer pore size.

Chromatographic system

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

Mode: LC

Detector: UV 195 nm

Column: 4.6-mm $\times$ 15-cm; 5- μ m packing L8

Column temperature: 35°

Flow rate: 1.5 mL/min

Injection size: 10 μ L

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

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0 for the glucosamine peak

Column efficiency: NLT 1500 theoretical plates

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of glucosamine ($C_6H_{13}NO_5$) in the portion of Tablets taken:

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

r_U = peak response of glucosamine from the *Sample solution*

r_s = peak response of glucosamine from the *Standard solution*

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

C_u = nominal concentration of glucosamine in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of glucosamine, 179.17

M_{r2} = molecular weight of glucosamine hydrochloride, 215.63

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

- [DISINTEGRATION AND DISSOLUTION OF DIETARY SUPPLEMENTS \(2040\)](#): Meet the requirements for *Dissolution*

Medium: Water; 900 mL

Apparatus 2: 75 rpm

Time: 60 min

Standard solution: Dissolve a suitable amount of [USP Glucosamine Hydrochloride RS](#) in water to obtain a concentration similar to that expected in the *Sample solution*.

Sample solution: Filtered portion of the solution under test

Buffer: Mix 1.0 mL of phosphoric acid with 2 L of water, and adjust with potassium hydroxide to a pH of 3.0.

Mobile phase: Acetonitrile and *Buffer* (2:3)

Chromatographic system

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

Mode: LC

Detector: UV 195 nm

Column: 4.6-mm × 25-cm; packing L7

Flow rate: 0.6 mL/min

Injection size: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0 for the glucosamine peak

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of glucosamine ($C_6H_{13}NO_5$) dissolved:

$$\text{Result} = (r_u/r_s) \times (C_s \times V/L) \times (M_{r1}/M_{r2}) \times 100$$

r_u = peak area from the *Sample solution*

r_s = peak area from the *Standard solution*

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

V = volume of *Medium*, 900 mL

L = labeled amount of glucosamine (mg/Tablet)

M_{r1} = molecular weight of glucosamine, 179.17

M_{r2} = molecular weight of glucosamine hydrochloride, 215.63

Tolerances: NLT 75% of the labeled amount of glucosamine ($C_6H_{13}NO_5$) is dissolved.

- [WEIGHT VARIATION OF DIETARY SUPPLEMENTS \(2091\)](#): Meet the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.
- **LABELING:** The label indicates the type of glucosamine salt contained in the article.
- [USP REFERENCE STANDARDS \(11\)](#).