N-Acetylglucosamine

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Expert Committee	Non-Botanical Dietary Supplements

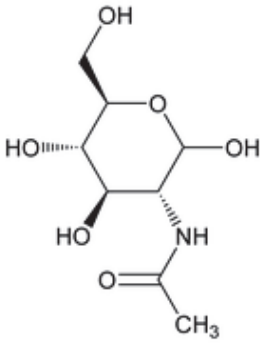
In accordance with the Rules and Procedures of the 2015–2020 Council of Experts, the Non-Botanical Dietary Supplements Expert Committee has revised the *N*-Acetylglucosamine monograph. The purpose for the revision is to address the comments received from the industry. The *Standard solution* and *Sample* size for the *Chloride and Sulfate <221>, Chloride* test were omitted from the monograph. To correct the error, the *Standard solution* and *Sample* size have been added as required by general chapter *<221> Chloride and Sulfate.*

The *N*-Acetylglucosamine Revision Bulletin supersedes the currently official monograph.

Should you have any questions, please contact Fatkhulla Tadjimukhamedov, Scientific Liaison to the Non-Botanical Dietary Supplements Expert Committee (fkt@usp.org).

Revision Bulletin
Official: June 1, 2020

N-Acetylglucosamine



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$C_8H_{15}NO_6$ 221.21
2-(Acetylamino)-2-deoxy-D-glucose;
N-Acetyl-D-Glucosamine [7512-17-6].

DEFINITION

N-Acetylglucosamine contains NLT 98.0% and NMT 102.0% of *N*-acetylglucosamine ($C_8H_{15}NO_6$), calculated on the dried basis.

IDENTIFICATION

- **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197K
- **B.** It meets the requirements in the test for *Optical Rotation ⟨781S⟩, Procedures, Specific Rotation*.
- **C.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

- **Procedure**

Buffer: Transfer 3.5 g of dibasic potassium phosphate to a 1-L volumetric flask, and add sufficient water to dissolve. 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)

System suitability solution: 1.0 mg/mL of USP *N*-Acetylglucosamine RS and 0.6 mg/mL of USP Glucosamine Hydrochloride RS in *Diluent*

Standard solution: 1.0 mg/mL of USP *N*-Acetylglucosamine RS in *Diluent*

Sample solution: 1.0 mg/mL of *N*-Acetylglucosamine in *Diluent*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 195 nm

Column: 4.6-mm × 15-cm; 3-µm packing L8

Column temperature: 35°

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

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

[Note—The relative retention times for *N*-acetylglucosamine and glucosamine are 1.0 and about 2.8, respectively.]

Suitability requirements

Signal-to-noise ratio: NLT 10 for the glucosamine peak, *System suitability solution*

Resolution: NLT 5.0 between the *N*-acetylglucosamine and glucosamine peaks, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of *N*-acetylglucosamine ($C_8H_{15}NO_6$) in the portion of *N*-Acetylglucosamine 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 *N*-Acetylglucosamine RS in the *Standard solution* (mg/mL)

C_U = concentration of *N*-Acetylglucosamine in the *Sample solution* (mg/mL)

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

IMPURITIES

- **Residue on Ignition** ⟨281⟩**:** NMT 0.1%

Change to read:

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

▲Standard solution: 0.4 mL of 0.020 N hydrochloric acid

Sample: 0.3 g of *N*-acetylglucosamine

Acceptance criteria: NMT 0.1%▲ (RB 1-Jun-2020)

- **Elemental Impurities—Procedures** ⟨233⟩

Acceptance criteria

Arsenic: NMT 1 µg/g

Lead: NMT 10 µg/g

- **Related Compounds**

Buffer, Mobile phase, Diluent, System suitability solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Sample solution: 2.5 mg/mL of *N*-Acetylglucosamine in *Diluent*

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of *N*-Acetylglucosamine taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of each impurity from the *Sample solution*

r_T = sum of the peak responses from the *Sample solution*

Acceptance criteria

Individual impurity: NMT 0.5%

Total impurities: NMT 2.0%

- **Limit of Glucosamine**

Buffer, Mobile phase, Diluent, System suitability solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Standard solution: 0.6 mg/mL of USP Glucosamine Hydrochloride RS in *Diluent*

Sample solution: 50 mg/mL of *N*-Acetylglucosamine in *Diluent*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of glucosamine in the portion of *N*-Acetylglucosamine taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_1/M_2) \times 100$$

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 = concentration of *N*-Acetylglucosamine in the *Sample solution* (mg/mL)

M_1 = molecular weight of glucosamine, 179.17

M_2 = molecular weight of glucosamine hydrochloride, 215.63

Acceptance criteria: NMT 1.0%

SPECIFIC TESTS

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

  Sample solution: 20 mg/mL in water, perform the measurement 3 h after sample preparation.

  Acceptance criteria: +39.0° to +43.0°
- **pH** ⟨791⟩

  Sample solution: 10 mg/mL in water

  Acceptance criteria: 6.0–8.0
- **Loss on Drying** ⟨731⟩

  Analysis: Dry a sample at 105° for 2 h.

  Acceptance criteria: NMT 0.5%
- **Melting Range or Temperature** ⟨741⟩**:** 196°–205°
- **Microbial Enumeration Tests** ⟨2021⟩**:** The total aerobic bacterial count does not exceed 10^3 cfu/g; the total combined molds and yeasts count does not exceed 10^3 cfu/g.
- **Absence of Specified Microorganisms** ⟨2022⟩**:** Meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers.
- **USP Reference Standards** ⟨11⟩

  USP *N*-Acetylglucosamine RS

  USP Glucosamine Hydrochloride RS

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