

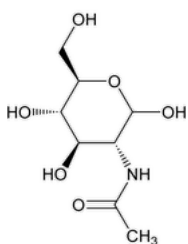
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N-Acetylglucosamine

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$C_8H_{15}NO_6$ 221.21

2-(Acetylamino)-2-deoxy-D-glucose;

N-Acetyl-D-Glucosamine CAS RN®: 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](#)