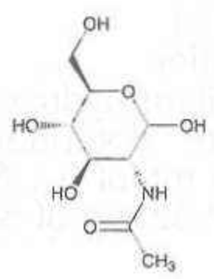
# Dietary Supplements

## Official Monographs

## *N*-Acetylglucosamine



$C_8H_{15}NO_6$ 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. Infrared Absorption** ⟨197K⟩
- **B.** It meets the requirements in the test for *Optical Rotation* ⟨781S⟩, *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%
- **Chloride and Sulfate,** *Chloride* ⟨221⟩**:** NMT 0.1%
- **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*