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,** *Specific Rotation* ⟨**781S**⟩

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*

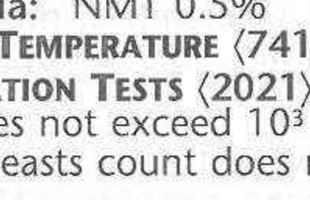
ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.
- **USP REFERENCE STANDARDS** ⟨**11**⟩

USP *N*-Acetylglucosamine RS
USP Glucosamine Hydrochloride RS

DS Monographs

N-Acetyltyrosine



$C_{11}H_{13}NO_4$ 223.2
N-Acetyl-L-tyrosine;
(2*S*)-2-(Acetylamino)-3-(4-hydroxyphenyl)propanoic acid) [537-55-3].

DEFINITION

N-Acetyltyrosine contains NLT 98.5% and NMT 101.0% of *N*-acetyltyrosine ($C_{11}H_{13}NO_4$), as *N*-acetyl-L-tyrosine, calculated on the dried basis.

IDENTIFICATION

- **A. INFRARED ABSORPTION** ⟨**197K**⟩
- **B. OPTICAL ROTATION,** *Specific Rotation* ⟨**781S**⟩

Sample solution: 10 mg/mL
Acceptance criteria: NLT +46.0° and NMT +49.0°, determined at 20°

- **C.** The R_F value of the principal spot of the *Sample solution* in the test for *Organic Impurities* corresponds to that of *Standard solution 1*.

ASSAY

- **PROCEDURE**

Sample solution: Dissolve about 180 mg of *N*-Acetyltyrosine, weighed, in 50 mL of carbon dioxide-free water.
Titrimetric system
(See *Titrimetry* ⟨541⟩.)
Mode: Direct titration
Titrant: 0.1 N sodium hydroxide VS
Endpoint detection: Potentiometric
Equivalency: Each mL of 0.1 N sodium hydroxide VS is equivalent to 22.32 mg of *N*-acetyltyrosine ($C_{11}H_{13}NO_4$).

IMPURITIES

- **RESIDUE ON IGNITION** ⟨**281**⟩**:** NMT 0.1%
- **CHLORIDE AND SULFATE,** *Chloride* ⟨**221**⟩

Sample: 0.7 g
Standard: 0.40 mL of 0.01 N hydrochloric acid
Acceptance criteria: NMT 200 ppm

- **CHLORIDE AND SULFATE,** *Sulfate* ⟨**221**⟩

Sample: 1.2 g
Standard: 0.25 mL of 0.020 N sulfuric acid
Acceptance criteria: NMT 200 ppm

- **IRON** ⟨**241**⟩**:** NMT 20 ppm

Delete the following:

- **HEAVY METALS,** *Method 1* ⟨**231**⟩**:** NMT 10 ppm (Official 1-Jan-2018)

- **ORGANIC IMPURITIES**

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture
Standard stock solution 1: 8 mg/mL of USP *N*-Acetyl-L-tyrosine RS in a mixture of water, glacial acetic acid, and alcohol (3:3:94)
Standard solution 1: Dilute *Standard stock solution 1* with alcohol to obtain a solution having a known concentration of about 0.4 mg/mL.
Standard solution 2: 0.8 mg/mL of USP L-Tyrosine RS dissolved in a mixture of glacial acetic acid and water (1:1), and diluted with alcohol
Sample solution: Transfer 0.8 g of *N*-Acetyltyrosine to a 10-mL volumetric flask, dissolve in 6 mL of a mixture of glacial acetic acid and water (1:1), and dilute with alcohol to volume.
Application volume: 5 µL
Developing solvent system: A mixture of ammonia and 2-propanol (3:7)
Spray reagent: Dissolve 0.2 g of ninhydrin in 100 mL of a mixture of butanol and 2 N acetic acid (95:5).
Analysis: Proceed as directed for *Chromatography* ⟨621⟩, *Thin-Layer Chromatography*. After air-drying the plate, repeat the development process. After air-drying a second time, examine the plate under short-wave UV light, and record principal and secondary spots. Spray the plate with *Spray reagent*, and heat between 100° and 105° for about 15 min. Examine the plate under white light, and record the principal and secondary spots.