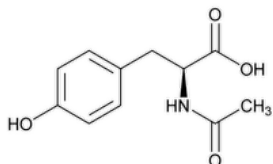


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N-Acetyltyrosine



$C_{11}H_{13}NO_4$ 223.2

N-Acetyl-L-tyrosine;

(2S)-2-(Acetylamino)-3-(4-hydroxyphenyl)propanoic acid) CAS RN®: 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. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy: 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

Change to read:

- **▲IRON (241), Procedures, Procedure 1▲** (CN 1-JUN-2023) : NMT 20 ppm

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.

Acceptance criteria: Under the short-wave UV light, any secondary spot observed from the *Sample solution* is not larger or more intense than the principal spot from *Standard solution 1*. After applying the *Spray reagent*, under white light, any secondary spot at the locus of tyrosine from the *Sample solution* is not larger or more intense than the principal spot from *Standard solution 2*.

Individual impurities: NMT 0.5%

Limit of tyrosine: NMT 1.0%

SPECIFIC TESTS

- [Loss on Drying \(731\)](#)
Analysis: Dry a sample at 105° for 3 h.
Acceptance criteria: NMT 0.1%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, and store at controlled room temperature.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP N-Acetyl-L-tyrosine RS](#)
[USP L-Tyrosine RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
N-ACETYLTYROSINE	Fatkhulla K Tadjimukhamedov Associate Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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