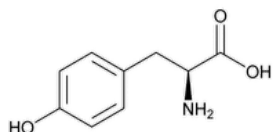


Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-Jun-2023
Document Type: USP Monographs
DocId: GUID-76C6278A-C03C-4E12-A0C7-0CEAB4216162_5_en-US
DOI: https://doi.org/10.31003/USPNF_M87220_05_01
DOI Ref: cyv3d

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Tyrosine



$C_9H_{11}NO_3$ 181.19

L-Tyrosine CAS RN®: 60-18-4; UNII: 42HK56048U.

DEFINITION

Tyrosine contains NLT 98.5% and NMT 101.5% of L-tyrosine ($C_9H_{11}NO_3$), calculated on the dried basis.

IDENTIFICATION

- A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#)

ASSAY

• PROCEDURE

Sample: 180 mg of Tyrosine

Blank: Mix 6 mL of formic acid and 50 mL of glacial acetic acid.

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: 0.1 N perchloric acid VS

Endpoint detection: Potentiometric

Analysis: Dissolve the *Sample* in 6 mL of formic acid and 50 mL of glacial acetic acid, and titrate with the *Titrant*. Perform the *Blank* determination.

Calculate the percentage of tyrosine ($C_9H_{11}NO_3$) in the *Sample* taken:

$$\text{Result} = \{(V_s - V_b) \times N \times F\} / W \times 100$$

V_s = volume of *Titrant* consumed by the *Sample* (mL)

V_b = volume of *Titrant* consumed by the *Blank* (mL)

N = actual normality of the *Titrant* (mEq/mL)

F = equivalency factor, 181.2 mg/mEq

W = *Sample* weight (mg)

Acceptance criteria: 98.5%–101.5% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.4%

- [CHLORIDE AND SULFATE, Chloride \(221\)](#)

Standard solution: 0.20 mL of 0.020 N hydrochloric acid

Sample: 0.35 g of Tyrosine. [NOTE—If necessary, dissolve the *Sample* by heating to near boiling and adding 1 mL of nitric acid.]

Acceptance criteria: NMT 0.04%

- [CHLORIDE AND SULFATE, Sulfate \(221\)](#)

Standard solution: 0.50 mL of 0.020 N sulfuric acid

Sample: 1.2 g of Tyrosine. [NOTE—If necessary, dissolve the *Sample* by adding 6 mL of diluted hydrochloric acid.]

Acceptance criteria: NMT 0.04%

Change to read:

- ▲ [IRON \(241\), Procedures, Procedure 1](#) ▲ (CN 1-JUN-2023) : NMT 30 ppm. [NOTE—If necessary, use 2 mL of hydrochloric acid to dissolve the *Sample*.]

• **RELATED COMPOUNDS**

Diluted ammonia solution: Dilute 16 mL of concentrated ammonia with water to 100 mL.

System suitability solution: Dissolve 10 mg of [USP L-Tyrosine RS](#) and 10 mg of [USP L-Phenylalanine RS](#) in 1 mL of *Diluted ammonia solution*, and dilute with water to 25.0 mL.

Standard solution: In a suitable flask, dissolve a quantity of [USP L-Tyrosine RS](#) in 1 mL of *Diluted ammonia solution*. Dilute with water to volume to obtain a solution of 0.05 mg/mL. [NOTE—This solution has a concentration equivalent to 0.5% of that of the *Sample solution*.]

Sample solution: Transfer 0.1 g of Tyrosine into a 10-mL volumetric flask, add sufficient *Diluted ammonia solution* to dissolve, and dilute with water to volume.

Chromatographic system

(See [Chromatography \(621\), Thin-Layer Chromatography](#).)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 5 µL

Developing solvent system: Isopropyl alcohol and ammonium hydroxide (7:3)

Spray reagent: 2 mg/mL of ninhydrin in a mixture of butyl alcohol and 2 N acetic acid (95:5)

System suitability

Suitability requirements: The chromatogram of the *System suitability solution* exhibits two clearly separated spots.

Analysis

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

Dry the plate between 100° and 105° until the ammonia disappears completely. Spray with *Spray reagent*, and heat between 100° and 105° for 15 min. Examine the plate under white light.

Acceptance criteria: Any secondary spot of the *Sample solution* is not larger or more intense than the principal spot of the *Standard solution*.

Any individual impurity: NMT 0.5%

Total impurities: NMT 2.0%

SPECIFIC TESTS

- [OPTICAL ROTATION, Specific Rotation \(781S\)](#)

Sample solution: 50 mg/mL in 1 N hydrochloric acid

Acceptance criteria: −9.8° to −11.2°

- [LOSS ON DRYING \(731\)](#): Dry a sample at 105° for 3 h: it loses NMT 0.3% of its weight.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.

- [USP REFERENCE STANDARDS \(11\)](#)

[USP L-Phenylalanine RS](#)

[USP L-Tyrosine RS](#)

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

Topic/Question	Contact	Expert Committee
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REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 32(6)

Current DocID: GUID-76C6278A-C03C-4E12-A0C7-0CEAB4216162_5_en-US

DOI: https://doi.org/10.31003/USPNF_M87220_05_01

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