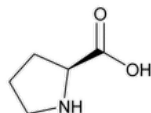


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Proline



$C_5H_9NO_2$ 115.13

L-Proline CAS RN®: 147-85-3; UNII: 9DLQ4CIU6V.

DEFINITION

Proline contains NLT 98.5% and NMT 101.5% of L-proline ($C_5H_9NO_2$), calculated on the dried basis.

IDENTIFICATION

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

ASSAY

• PROCEDURE

Sample: 100 mg of Proline

Blank: Mix 3 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 3 mL of formic acid and 50 mL of glacial acetic acid. Titrate with the *Titrant*. Perform the *Blank* determination.

Calculate the percentage of proline ($C_5H_9NO_2$) 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, 115.1 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: 0.50 mL of 0.020 N hydrochloric acid

Sample: 0.73 g of Proline

Acceptance criteria: NMT 0.05%

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

Standard solution: 0.10 mL of 0.020 N sulfuric acid

Sample: 0.33 g of Proline

Acceptance criteria: NMT 0.03%

Change to read:

• ▲ **IRON (241), Procedures, Procedure 1** ▲ (CN 1-JUN-2023) : NMT 30 ppm

• **RELATED COMPOUNDS**

System suitability solution: 0.4 mg/mL each of [USP L-Proline RS](#) and [USP L-Threonine RS](#) in 0.1 N hydrochloric acid

Standard solution: 0.05 mg/mL of [USP L-Proline RS](#) in 0.1 N hydrochloric acid. [NOTE—This solution has a concentration equivalent to 0.5% of that of the *Sample solution*.]

Sample solution: 10 mg/mL of Proline in 0.1 N hydrochloric acid

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: Butyl alcohol, glacial acetic acid, and water (3:1:1)

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*

After air-drying the plate, 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*.

Individual impurities: NMT 0.5%

Total impurities: NMT 2.0%

SPECIFIC TESTS

• **OPTICAL ROTATION, Specific Rotation (781S).**

Sample solution: 40 mg/mL in water

Acceptance criteria: –84.3° to –86.3°

• **LOSS ON DRYING (731):** Dry a sample at 105° for 3 h: it loses NMT 0.4% of its weight.

ADDITIONAL REQUIREMENTS

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

• **USP REFERENCE STANDARDS (11).**

[USP L-Proline RS](#)

[USP L-Threonine RS](#)

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

Topic/Question	Contact	Expert Committee
PROLINE	Fatkhulla K Tadjimukhamedov Associate Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
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. Information currently unavailable

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