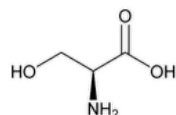


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Serine



$C_3H_7NO_3$ 105.09

L-Serine CAS RN®: 56-45-1; UNII: 452VLY9402.

DEFINITION

Serine contains NLT 98.5% and NMT 101.5% of L-serine ($C_3H_7NO_3$), calculated on the dried basis.

IDENTIFICATION

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

ASSAY

• PROCEDURE

Sample: 100 mg of Serine

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 serine ($C_3H_7NO_3$) in the *Sample* taken:

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

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

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

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

F = equivalency factor, 105.1 mg/mEq

W = *Sample* weight (mg)

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

IMPURITIES

- **[RESIDUE ON IGNITION \(281\)](#):** NMT 0.1%

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

Standard solution: 0.50 mL of 0.020 N hydrochloric acid

Sample: 0.73 g of Serine

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 Serine

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-Serine RS](#) and [USP L-Methionine RS](#) in 0.1 N hydrochloric acid

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

Sample solution: 10 mg/mL of Serine 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: 100 mg/mL in 2 N hydrochloric acid

Acceptance criteria: +14.0° to +15.6°

- **LOSS ON DRYING (731):** Dry a sample at 105° for 3 h: it loses NMT 0.2% of its weight.

ADDITIONAL REQUIREMENTS

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

- **USP REFERENCE STANDARDS (11)**

[USP L-Methionine RS](#)

[USP L-Serine RS](#)

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

Topic/Question	Contact	Expert Committee
SERINE	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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