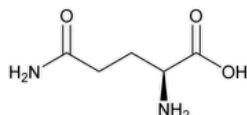


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Glutamine



$C_5H_{10}N_2O_3$ 146.14

L-Glutamine;

2-Aminoglutaric acid CAS RN[®]: 56-85-9; UNII: 0RH81L854J.

DEFINITION

Glutamine contains NLT 98.5% and NMT 101.5% of L-glutamine ($C_5H_{10}N_2O_3$), calculated on the dried basis.

IDENTIFICATION

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

ASSAY

• PROCEDURE

Sample: 150 mg of Glutamine

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, and titrate with the *Titrant*. Perform a *Blank* determination.

Calculate the percentage of glutamine ($C_5H_{10}N_2O_3$) 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, 146.1 mg/mEq

W = *Sample* weight (mg)

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

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.3%

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

Standard solution: 0.50 mL of 0.020 N hydrochloric acid

Sample: 0.7 g of Glutamine

Acceptance criteria: NMT 0.05%

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

Standard solution: 0.25 mL of 0.020 N sulfuric acid

Sample: 0.8 g of Glutamine

Acceptance criteria: NMT 0.03%

Change to read:

- ▲ [IRON \(241\), Procedures, Procedure 1](#) ▲ (CN 1-JUN-2023) : NMT 30 ppm

• **RELATED COMPOUNDS**

Standard solution: 0.05 mg/mL of [USP Glutamine RS](#) in water

Sample solution: 10 mg/mL of Glutamine in water

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)

Analysis: Dry the plate at 80° for 30 min. Spray the plate with *Spray reagent*, heat at 80° for 10 min, and examine under white light.

Acceptance criteria: No secondary spot of the *Sample solution* is larger or more intense than the principal spot of the *Standard solution* (NMT 0.5%).

SPECIFIC TESTS

- [OPTICAL ROTATION, Specific Rotation\(781S\)](#)
- Sample solution:** 40 mg/mL in water. Warm at 40° to dissolve.
- Analysis:** Proceed as directed in the chapter, except measure at 20°.
- Acceptance criteria:** +6.3° to +7.3°
- [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, and store at controlled room temperature.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP Glutamine RS](#)

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

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

Chromatographic Database Information: [Chromatographic Database](#)

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