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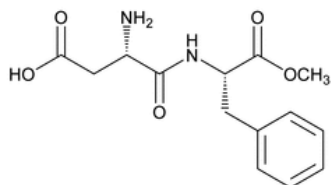
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# Aspartame



$C_{14}H_{18}N_2O_5$  294.30

L-Phenylalanine, N-L-α-aspartyl-, 1-methyl ester;

3-Amino-N-(α-carboxyphenethyl)succinamic acid N-methyl ester CAS RN<sup>®</sup>: 22839-47-0.

## DEFINITION

Aspartame contains NLT 98.0% and NMT 102.0% of aspartame ( $C_{14}H_{18}N_2O_5$ ), calculated on the dried basis.

## IDENTIFICATION

Change to read:

- A. [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197M](#) ▲ (CN 1-MAY-2020)

[NOTE—Do not dry specimens.]

## ASSAY

### • PROCEDURE

Buffer: 0.05 M monobasic potassium phosphate, adjusted with phosphoric acid to a pH of 4.3

Mobile phase: Methanol and Buffer (18:82)

Diluent: Methanol and water (1:9)

System suitability solution: 0.1 mg/mL each of [USP Aspartame Related Compound A RS](#) and [USP L-Phenylalanine RS](#) in Diluent

Standard solution: 0.5 mg/mL of [USP Aspartame RS](#) in Diluent

Sample solution: 0.5 mg/mL of Aspartame in Diluent. [NOTE—Avoid heat and excessive holding times.]

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; 5-μm packing L1

Column temperature: 40°

Flow rate: 2 mL/min

Injection volume: 20 μL

Run time: 30 min

System suitability

Samples: System suitability solution and Standard solution

[NOTE—The relative retention times for the L-phenylalanine and aspartame related compound A peaks are 0.6 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 8 between the L-phenylalanine and aspartame related compound A peaks, System suitability solution

Tailing factor: NMT 1.5, Standard solution

Relative standard deviation: NMT 1.0%, Standard solution

Analysis

Samples: Standard solution and Sample solution

Calculate the percentage of aspartame ( $C_{14}H_{18}N_2O_5$ ) in the portion of Aspartame taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

$r_U$  = peak area of aspartame from the *Sample solution*

$r_S$  = peak area of aspartame from the *Standard solution*

$C_S$  = concentration of [USP Aspartame RS](#) in the *Standard solution* (mg/mL)

$C_U$  = concentration of Aspartame in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

## IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%

- LIMIT OF 5-BENZYL-3,6-DIOXO-2-PIPERAZINEACETIC ACID

Mobile phase, Diluent, System suitability solution, and Chromatographic system: Proceed as directed in the Assay.

Standard solution: 75 µg/mL of [USP Aspartame Related Compound A RS](#) in *Diluent*

Sample solution: 5 mg/mL of Aspartame in *Diluent*. [NOTE—Avoid heat and excessive holding times.]

System suitability

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

Suitability requirements

Resolution: NLT 8 between the L-phenylalanine and aspartame related compound A peaks, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 4.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

[NOTE—Continue the elution of the *Sample solution* for 45 min.]

Calculate the percentage of aspartame related compound A in the portion of Aspartame taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

$r_U$  = peak response of aspartame related compound A from the *Sample solution*

$r_S$  = peak response of aspartame related compound A from the *Standard solution*

$C_S$  = concentration of 5-benzyl-3,6-dioxo-2-piperazineacetic acid in the *Standard solution* (mg/mL)

$C_U$  = concentration of Aspartame in the *Sample solution* (mg/mL)

Acceptance criteria: NMT 1.5%

- CHROMATOGRAPHIC PURITY

Mobile phase, Diluent, System suitability solution, and Chromatographic system: Proceed as directed in the Assay.

Sample stock solution: Proceed as directed in the *Sample solution* in the test for *Limit of 5-Benzyl-3,6-dioxo-2-piperazineacetic Acid*.

Sample solution: 0.1 mg/mL of Aspartame from the *Sample stock solution* in *Diluent*

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 8 between the L-phenylalanine and aspartame related compound A peaks, *System suitability solution*

Analysis

Samples: *Sample stock solution* and *Sample solution*

[NOTE—Continue the elution of the *Sample stock solution* for 45 min.]

Acceptance criteria: The sum of all of the peak responses of the *Sample stock solution*, excluding the 5-benzyl-3,6-dioxo-2-piperazineacetic acid and aspartame peak responses, is NMT the aspartame peak response of the *Sample solution*, corresponding to NMT 2.0% of chromatographic impurities.

## SPECIFIC TESTS

- TRANSMITTANCE

Sample solution: 10 mg/mL of Aspartame in 2 N hydrochloric acid, prepared by means of sonication

Analysis: Determine the transmittance in a 1-cm cell at 430 nm with a suitable spectrophotometer.

Acceptance criteria: Transmittance of NLT 0.95, corresponding to an absorbance of NMT about 0.022

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

Sample solution: 40 mg/mL in 15 N formic acid

Acceptance criteria: +14.5° to +16.5°, determined at 20° within 30 min after preparation of the *Sample solution*

• [LOSS ON DRYING \(731\)](#)

Analysis: Dry at 105° for 4 h.

Acceptance criteria: NMT 4.5%

ADDITIONAL REQUIREMENTS

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

• [USP REFERENCE STANDARDS \(11\)](#)

[USP Aspartame RS](#)

[USP Aspartame Related Compound A RS](#)

5-Benzyl-3,6-dioxo-2-piperazineacetic acid.

$C_{13}H_{14}N_2O_4$  262.27

[USP L-Phenylalanine RS](#)

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

| Topic/Question              | Contact                                                                     | Expert Committee                |
|-----------------------------|-----------------------------------------------------------------------------|---------------------------------|
| ASPARTAME                   | <a href="#">Documentary Standards Support</a>                               | EXC12025 Excipient Monographs 1 |
| REFERENCE STANDARDS SUPPORT | RS Technical Services<br><a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a> | EXC12025 Excipient Monographs 1 |

**Chromatographic Database Information:** [Chromatographic Database](#)

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