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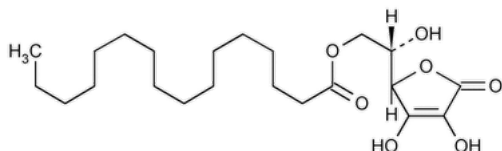
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Ascorbyl Palmitate


 $C_{22}H_{38}O_7$ 414.53

L-Ascorbic acid, 6-hexadecanoate;

L-Ascorbic acid 6-palmitate CAS RN®: 137-66-6.

DEFINITION

Ascorbyl Palmitate contains NLT 95.0% and NMT 100.5% of ascorbyl palmitate ($C_{22}H_{38}O_7$), calculated on the dried basis.

IDENTIFICATION

Change to read:

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

• **B. CHROMATOGRAPHIC IDENTITY**

Analysis: Proceed as directed in the Assay.

Acceptance criteria: The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*.

ASSAY

• PROCEDURE

Mobile phase: Acetonitrile, methanol, 0.01 M perchloric acid (10:65:25)

Standard solution: 0.5 mg/mL of [USP Ascorbyl Palmitate RS](#) in methanol

Sample solution: 0.5 mg/mL of Ascorbyl Palmitate in methanol

Chromatographic system

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

Mode: LC

Detector: UV 245 nm

Column: 4.6-mm × 15-cm; 5-μm packing L7

Temperatures

Column: 25°

Autosampler: 5°

[NOTE—If an autosampler is not used, keep the *Standard solution* and *Sample solution* at 5° before injection.]

Flow rate: 1.0 mL/min

Injection volume: 10 μL

Run time: 15 min

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 1.0%

Tailing factor: 0.8–2.0

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate, on the dried basis, the percentage of Ascorbyl Palmitate taken:

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

r_U = peak response from the *Sample solution*

r_s = peak response from the *Standard solution*

C_s = concentration of [USP Ascorbyl Palmitate RS](#) in the *Standard solution* (mg/mL)

C_u = concentration of Ascorbyl Palmitate in the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–100.5% on the dried basis

IMPURITIES

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

SPECIFIC TESTS

- [OPTICAL ROTATION, Specific Rotation \(781S\)](#): +21° to +24°

Sample solution: 100 mg/mL in methanol

- [LOSS ON DRYING \(731\)](#)

Analysis: Dry a sample in vacuum at 60° for 1 h.

Acceptance criteria: NMT 2.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, and store in a cool, dry place.

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

[USP Ascorbyl Palmitate RS](#)

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

Topic/Question	Contact	Expert Committee
ASCORBYL PALMITATE	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 38(6)

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