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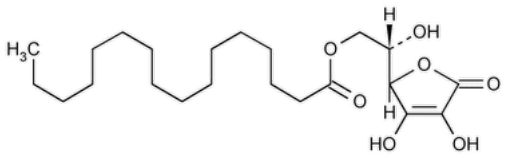
Ascorbyl Palmitate



$C_{22}H_{38}O_7$ 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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