

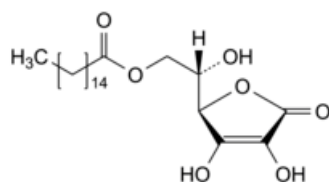


Edition: BP 2025 (Ph. Eur. 11.6 update)

Ascorbyl Palmitate

[General Notices](#)

(Ph. Eur. monograph 0807)



C₂₂H₃₈O₇ 414.5 137-66-6

Action and use

Excipient.

Ph Eur

DEFINITION

(2S)-2-[(2R)-3,4-Dihydroxy-5-oxo-2,5-dihydrofuran-2-yl]-2-hydroxyethyl hexadecanoate.

Content

98.0 per cent to 100.5 per cent (dried substance).

CHARACTERS

Appearance

White or yellowish-white powder.

Solubility

Practically insoluble in water, freely soluble in ethanol (96 per cent) and in methanol, practically insoluble in methylene chloride and in fatty oils.

IDENTIFICATION

- Specific optical rotation (see Tests).
- Infrared absorption spectrophotometry ([2.2.24](#)).

C. Dissolve about 10 mg in 5 mL of [methanol R](#). The solution decolourises [dichlorophenolindophenol standard solution R](#).

TESTS

Solution S

Dissolve 2.50 g in [methanol R](#) using sonication and dilute to 25.0 mL with the same solvent.

Appearance of solution

Solution S is clear ([2.2.1](#)) and not more intensely coloured than reference solution BY₄ ([2.2.2, Method I](#)).

[Specific optical rotation](#) ([2.2.7](#))

+ 21 to + 24 (dried substance), determined on solution S.

Related substances

The thresholds indicated under Related substances (Table 2034.-1) in the general monograph [Substances for pharmaceutical use \(2034\)](#) do not apply.

[Loss on drying](#) ([2.2.32](#))

Maximum 1.0 per cent, determined on 1.000 g by drying *in vacuo* at 60 °C for 5 h.

[Sulfated ash](#) ([2.4.14](#))

Maximum 0.1 per cent, determined on 1.0 g.

ASSAY

Dissolve 0.200 g in 50 mL of [ethanol \(96 per cent\) R](#). Add 30 mL of [water R](#) and titrate with [0.05 M iodine](#) until a yellow colour is obtained.

1 mL of [0.05 M iodine](#) is equivalent to 20.73 mg of C₂₂H₃₈O₇.

STORAGE

In an airtight container, protected from light.

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