A Ascorbyl Palmitate

1 Nonproprietary Names

BP: Ascorbyl Palmitate

PhEur: Ascorbyl Palmitate

USP–NF: Ascorbyl Palmitate

2 Synonyms

L-Ascorbic acid 6-palmitate; ascorbylis palmitas; E304; 3-oxo-L-gulofuranolactone 6-palmitate; Vitamin C ester; Vitamin C palmitate.

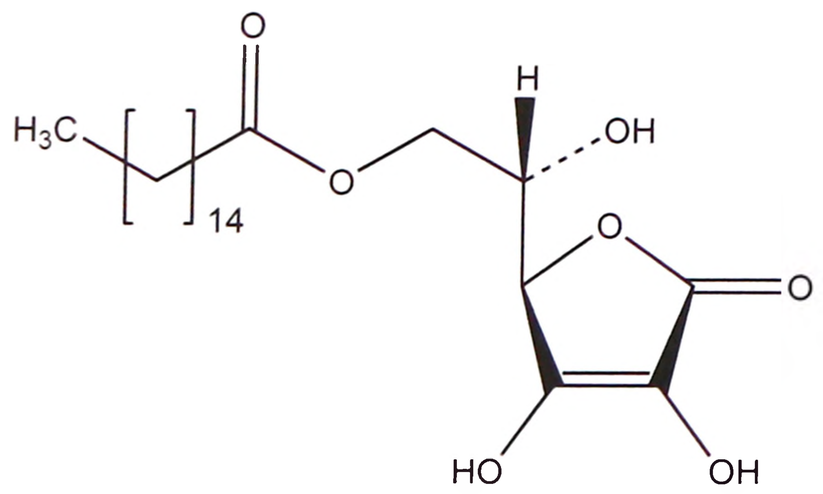
3 Chemical Name and CAS Registry Number

L-Ascorbic acid 6-hexadecanoate [137-66-6]

4 Empirical Formula and Molecular Weight

$C_{22}H_{38}O_7$ 414.54

5 Structural Formula



6 Functional Category

Antioxidant.

7 Applications in Pharmaceutical Formulation or Technology

Ascorbyl palmitate is primarily used alone or in combination with alpha tocopherol as a stabilizer for oils in oral pharmaceutical formulations and food products; generally, a concentration of 0.05% w/v is used. It may also be used in oral and topical preparations as an antioxidant for drugs unstable to oxygen. The combination of ascorbyl palmitate with alpha tocopherol shows marked synergism, which increases the effect of the components and allows the amount used to be reduced. The solubility of ascorbyl palmitate in alcohol (freely soluble) permits it to be used in both nonaqueous and aqueous systems and emulsions.

8 Description

Ascorbyl palmitate is a practically odorless, white to yellowish powder.

9 Pharmacopeial Specifications

See Table I.

10 Typical Properties

Solubility *see* Table II.[1]

Spectroscopy

IR spectrum *see* Figure 1.

NIR spectrum *see* Figure 2.

Raman spectrum *see* Figure 3.

Table I: Pharmacopeial specifications for ascorbyl palmitate.

Test	PhEur 9.2	USP 40–NF 35 S1
Characters	+	–
Identification	+	+
Appearance of solution	+	–
Melting range	–	107–117°C
Specific rotation (10% w/v in methanol)	+21° to +24°	+21° to +24°
Related substances	+	–
Loss on drying	≤1.0%	≤2.0%
Residue on ignition	–	≤0.1%
Sulfated ash	≤0.1%	–
Heavy metals	–	≤10 ppm
Assay (dried basis)	98.0–100.5%	95.0–100.5%

Table II: Solubility of ascorbyl palmitate.

Solvent	Solubility at 20°C unless otherwise stated[1]
Acetone	1 in 15
Chloroform	1 in 3300
	1 in 11 at 60°C
Cottonseed oil	1 in 1670
Ethanol	1 in 8
	1 in 1.7 at 70°C
Ethanol (95%)	1 in 9.3
Ethanol (50%)	1 in 2500
Ether	1 in 132
Methanol	1 in 5.5
	1 in 1.7 at 60°C
Olive oil	1 in 3300
Peanut oil	1 in 3300
Propan-2-ol	1 in 20
	1 in 5 at 70°C
Sunflower oil	1 in 3300
Water	Practically insoluble
	1 in 500 at 70°C
	1 in 100 at 100°C

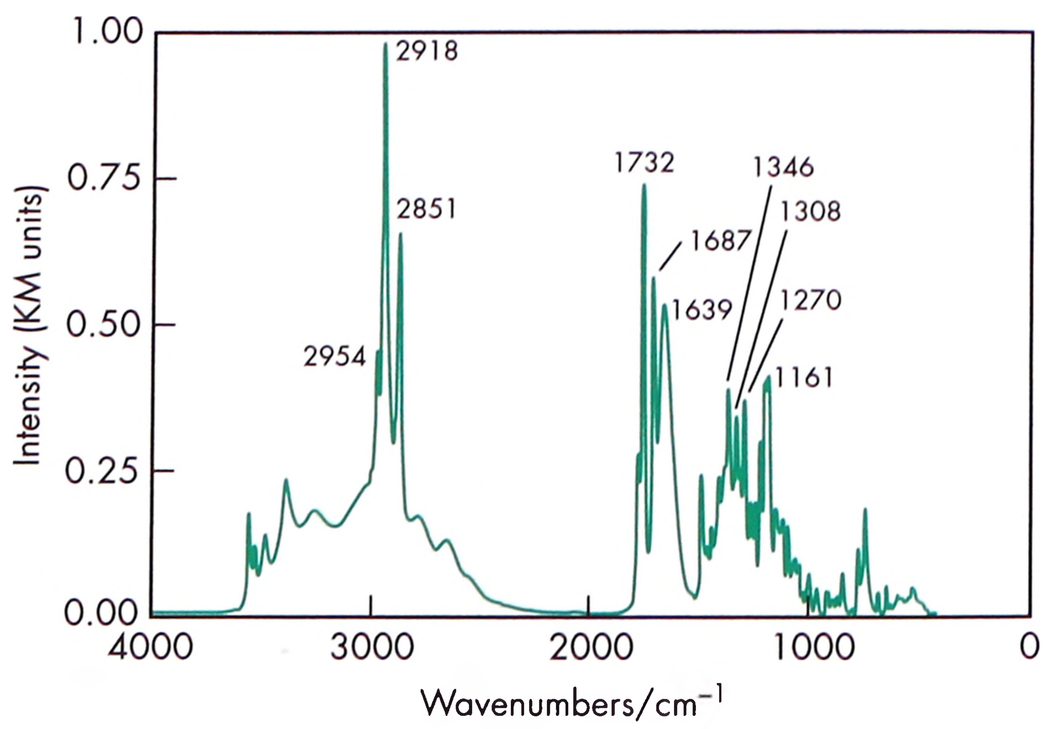


Figure 1: Infrared spectrum of ascorbyl palmitate measured by diffuse reflectance. Adapted with permission of Informa Healthcare.