

weigh it as the mass of phenytoin ($C_{15}H_{12}N_2O_2$: 252.27).

Amount (mg) of phenytoin sodium ($C_{15}H_{11}N_2NaO_2$)
= amount (mg) of phenytoin ($C_{15}H_{12}N_2O_2$) \times 1.0871

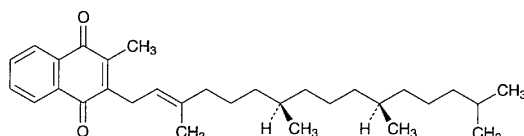
Containers and storage Containers—Hermetic containers.

Phytonadione

Phytomenadione

Vitamin K₁

フィトナジオン



$C_{31}H_{46}O_2$: 450.70

2-Methyl-3-[(2*E*,7*R*,11*R*)-3,7,11,15-tetramethylhexadec-2-en-1-yl]-1,4-naphthoquinone [84-80-0]

Phytonadione contains not less than 97.0% and not more than 102.0% of $C_{31}H_{46}O_2$.

Description Phytonadione is a clear yellow to orange-yellow, viscous liquid. It is odorless.

It is miscible with diethyl ether and with isooctane.

It is sparingly soluble in methanol and in ethanol (95), and practically insoluble in water.

It decomposes gradually and darkens by light.

Specific gravity d_{20}^{20} : about 0.967

Identification (1) Dissolve 0.05 g of Phytonadione in 10 mL of ethanol (95), and add 1 mL of a solution of potassium hydroxide in ethanol (95) (1 in 10): a blue color develops and changes to purple, then to brown upon standing.

(2) Dissolve 0.05 g of Phytonadione in 10 mL of a mixture of methanol and diethyl ether (1:1), add a freshly prepared solution of 0.75 g of sodium hydrosulfite in 2 mL of warm water, and shake vigorously: a yellow color disappears immediately.

(3) Determine the absorption spectrum of a solution of Phytonadione in isooctane (1 in 100,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum 1: both spectra exhibit similar intensities of absorption at the same wavelengths. Separately, determine the absorption spectrum of a solution of Phytonadione in isooctane (1 in 10,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum 2: both spectra exhibit similar intensities of absorption at the same wavelengths.

Refractive index n_D^{20} : 1.525 – 1.529

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Phytonadione in 10 mL of isooctane: the solution is clear, and shows a yellow color.

(2) Ratio of absorbances—Determine the absorbances, A_1 , A_2 and A_3 , of a solution of Phytonadione in isooctane (1 in 100,000) at 248.5 nm, 253.5 nm and 269.5 nm, respec-

tively: the ratio A_2/A_1 is between 0.69 and 0.73, and the ratio A_2/A_3 is between 0.74 and 0.78. Determine the absorbances, A_4 and A_5 , of a solution of Phytonadione in isooctane (1 in 10,000) at 284.5 nm and 326.0 nm, respectively: the ratio A_4/A_5 is between 0.28 and 0.34.

(3) Heavy metals—Carbonize 1.0 g of Phytonadione by gentle heating. Cool, add 10 mL of a solution of magnesium nitrate hexahydrate in ethanol (95) (1 in 10), and ignite the ethanol to burn. Cool, add 1 mL of sulfuric acid, proceed according to Method 4, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(4) Menadione—Dissolve 0.020 g of Phytonadione in 0.5 mL of a mixture of water and ethanol (95) (1:1), add 1 drop of a solution of 3-methyl-1-phenyl-5-pyrazolone in ethanol (95) (1 in 20) and 1 drop of ammonia solution (28), and allow to stand for 2 hours: no blue-purple color develops.

Assay Perform the test quickly under the protection from sunlight. Weigh accurately about 0.1 g of Phytonadione, dissolve in isooctane to make exactly 100 mL. Measure exactly 10 mL of this solution, and add isooctane to make exactly 100 mL. Pipet 10 mL of this solution, and add isooctane to make exactly 100 mL. Determine the absorbance A of this solution at the wavelength of maximum absorption at about 248.5 nm, as directed under the Ultraviolet-visible Spectrophotometry, adjusting the slit of the spectrophotometer to a band width of 0.5 nm.

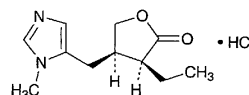
Amount (mg) of $C_{31}H_{46}O_2$ = $\frac{A}{422} \times 100,000$

Containers and storage Containers—Tight containers.

Storage—Light-resistant.

Pilocarpine Hydrochloride

塩酸ピロカルピン



$C_{11}H_{16}N_2O_2 \cdot HCl$: 244.72

(3*S*,4*R*)-3-Ethyldihydro-4-(1-methyl-1*H*-imidazol-5-ylmethyl)furan-2(3*H*)-one monohydrochloride [54-71-7]

Pilocarpine Hydrochloride, when dried, contains not less than 99.0% of $C_{11}H_{16}N_2O_2 \cdot HCl$.

Description Pilocarpine Hydrochloride occurs as colorless crystals or white powder. It is odorless, and has a slightly bitter taste.

It is very soluble in acetic acid (100), freely soluble in water, in methanol and in ethanol (95), soluble in acetic anhydride, and practically insoluble in diethyl ether.

The pH of a solution of Pilocarpine Hydrochloride (1 in 10) is between 3.5 and 4.5.

It is hygroscopic.

It is affected by light.

Identification (1) Dissolve 0.1 g of Pilocarpine