of tipepidine is about 7 minutes.

System suitability—

System performance: When the procedure is run with 20 μL of the standard solution under the above operating conditions, tipepidine and the internal standard are eluted in this order with the resolution between these peaks being not less than 10.

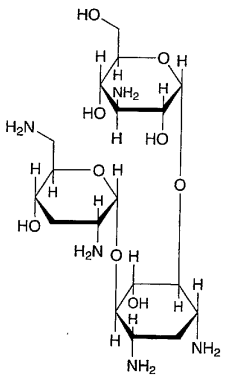
System repeatability: When the test is repeated 6 times with 20 μL of the standard solution under the above operating conditions, the relative standard deviation of the ratios of the peak area of tipepidine to that of the internal standard is not more than 1.0%.

Containers and storage Containers—Tight containers.

Storage—Light-resistant.

Tobramycin

トブラマイシン



$C_{18}H_{37}N_5O_9$: 467.51

O-3-Amino-3-deoxy-α-D-glucopyranosyl-(1→6)-*O*-[2,6-diamino-2,3,6-trideoxy-α-D-*ribo*-hexopyranosyl-(1→4)]-2-deoxy-D-streptamine [*32986-56-4*]

Tobramycin conforms to the requirements of Tobramycin in the Minimum Requirements for Antibiotic Products of Japan.

Description Tobramycin occurs as a white to pale yellowish white powder.

It is very soluble in water, slightly soluble in methanol, very slightly soluble in ethanol (95), and practically insoluble in diethyl ether.

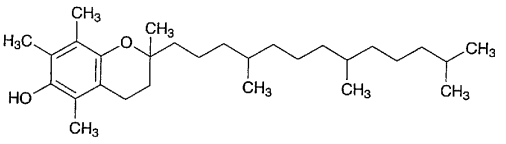
It is hygroscopic.

Tocopherol

Vitamin E

dl-α-Tocopherol

トコフェロール



$C_{29}H_{50}O_2$: 430.71

2,5,7,8-Tetramethyl-2-(4,8,12-trimethyltridecyl)chroman-6-ol [*10191-41-0*]

Tocopherol contains not less than 96.0% and not more than 102.0% of $C_{29}H_{50}O_2$.

Description Tocopherol is a clear, yellow to red-brown, viscous liquid. It is odorless.

It is miscible with ethanol (99.5), with acetone, with diethyl ether, with chloroform and with vegetable oils.

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

It is optically inactive.

It is oxidized by air and light, and acquires a dark red color.

Identification (1) Dissolve 0.01 g of Tocopherol in 10 mL of ethanol (99.5), add 2 mL of nitric acid, and heat at 75°C for 15 minutes: a red to orange color develops.

(2) Determine the infrared absorption spectrum of Tocopherol as directed in the liquid film method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of Tocopherol Reference Standard: both spectra exhibit similar intensities of absorption at the same wave numbers.

Absorbance $E^{1\%}_{1\,cm}$ (292 nm): 71.0 - 76.0 (0.01 g, ethanol (99.5), 200 mL).

Refractive index n_D^{20}: 1.503 - 1.507

Specific gravity d_{20}^{20}: 0.947 - 0.955

Purity (1) Clarity and color of solution—Dissolve 0.10 g of Tocopherol in 10 mL of ethanol (99.5): the solution is clear and has no more color than Matching Fluid C.

(2) Heavy metals—Proceed with 1.0 g of Tocopherol 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).

Assay Dissolve about 0.05 g each of Tocopherol and Tocopherol Reference Standard, accurately weighed, in ethanol (99.5) to make exactly 50 mL, and use these solutions as the sample solution and the standard solution. Pipet 20 μL each of these solutions, and perform the test as directed under the Liquid Chromatography according to the following conditions, and determine the peak heights, H_T and H_S, of tocopherol in the sample solution and the standard solution.

Amount (mg) of $C_{29}H_{50}O_2$
= amount (mg) of Tocopherol Reference Standard
$\times \frac{H_T}{H_S}$

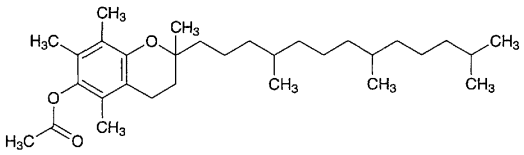
Operating conditions—
Detector: An ultraviolet absorption photometer (wavelength: 292 nm).
Column: A stainless steel column about 4 mm in inside diameter and 15 to 30 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 to 10 μL in particle diameter).
Column temperature: Room temperature.
Mobile phase: A mixture of methanol and water (49:1).
Flow rate: Adjust the flow rate so that the retention time of tocopherol is about 10 minutes.
Selection of column: Dissolve 0.05 g each of Tocopherol and tocopherol acetate in 50 mL of ethanol (99.5). Proceed with 20 μL of this solution under the above operating conditions, and calculate the resolution. Use a column giving elution of tocopherol and tocopherol acetate in this order with the resolution between these peaks being not less than 2.6.
System repeatability: Repeat the test five times with the standard solution under the above operating conditions: the relative standard deviation of the peak height of tocopherol is not more than 0.8%.

Containers and storage Containers—Tight containers.
Storage—Light-resistant, and well-filled, or under nitrogen atmosphere.

Tocopherol Acetate

Vitamin E Acetate
dl-α-Tocopherol Acetate

酢酸トコフェロール



$C_{31}H_{52}O_3$: 472.74
2,5,7,8-Tetramethyl-2-(4,8,12-trimethyltridecyl)chroman-6-yl acetate [*7695-91-2*]

Tocopherol Acetate contains not less than 96.0% and not more than 102.0% of $C_{31}H_{52}O_3$.

Description Tocopherol Acetate is a clear, colorless or yellow, viscous and odorless liquid.
It is miscible with ethanol (99.5), with acetone, with chloroform, with diethyl ether, with hexane and with fixed oils.
It is freely soluble in ethanol (95), and practically insoluble in water.
It is optically inactive.
It is affected by air and light.

Identification (1) Dissolve 0.05 g of Tocopherol Acetate in 10 mL of ethanol (99.5), add 2 mL of nitric acid, and heat at 75°C for 15 minutes: a red to orange color is produced.

(2) Determine the infrared absorption spectrum of Tocopherol Acetate as directed in the liquid film method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of Tocopherol Acetate Reference Standard: both spectra exhibit similar intensities of absorption at the same wave numbers.

Absorbance $E^{1\%}_{1\,cm}$ (284 nm): 41.0 - 45.0 (0.01 g, ethanol (99.5), 100 mL).

Refractive index n_D^{20}: 1.494 - 1.499

Specific gravity d_{20}^{20}: 0.952 - 0.966

Purity (1) Clarity and color of solution—Dissolve 0.10 g of Tocopherol Acetate in 10 mL of ethanol (99.5): the solution is clear, and has no more color than the following control solution.
Control solution: To 0.5 mL of Ferric Chloride Colorimetric Stock Solution add 0.5 mol/L hydrochloric acid TS to make 100 mL.
(2) Heavy metals—Carbonize 1.0 g of Tocopherol Acetate 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 (20 ppm).
(3) α-Tocopherol—Dissolve 0.10 g of Tocopherol Acetate in exactly 10 mL of hexane, and use this solution as the sample solution. Separately, dissolve 0.050 g of Tocopherol Reference Standard in hexane to make exactly 100 mL. Pipet 1 mL of this solution, add hexane to make exactly 10 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of toluene and acetic acid (100) (19:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly a solution of iron (III) chloride hexahydrate in ethanol (99.5) (1 in 500) on the plate, then spray evenly a solution of α,α′-dipyridyl in ethanol (99.5) (1 in 200) on the same plate, and allow to stand for 2 to 3 minutes: the spot from the sample solution corresponding to that from the standard solution is not larger than and not more intense than the spot from the standard solution.

Assay Dissolve 0.05 g each of Tocopherol Acetate and Tocopherol Acetate Reference Standard, accurately weighed, in ethanol (99.5) to make exactly 50 mL, and use these solutions as the sample solution and the standard solution. Pipet 20 μL each of these solutions, perform the test as directed under the Liquid Chromatography according to the following operating conditions, and determine the peak heights, H_T and H_S, of tocopherol acetate in the sample solution and the standard solution, respectively.

Amount (mg) of $C_{31}H_{52}O_3$
= amount (mg) of Tocopherol Acetate Reference Standard
$\times \frac{H_T}{H_S}$

Operating conditions—
Detector: An ultraviolet absorption photometer