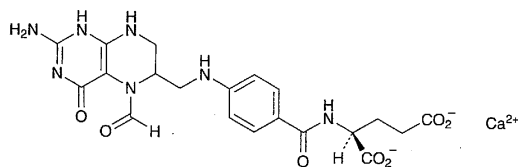


Calcium Folate

Calcium Leucovorin

ホリナートカルシウム



$C_{20}H_{21}CaN_7O_7$: 511.50

Monocalcium *N*-{4-[(2-amino-5-formyl-1,4,5,6,7,8-hexahydro-4-oxopteridin-6-yl)methylamino]benzoyl}-*L*-glutamate [1492-18-8]

Calcium Folate contains not less than 95.0% and not more than 102.0% of $C_{20}H_{21}CaN_7O_7$, calculated on the anhydrous basis.

Description Calcium Folate occurs as a light yellow to yellow powder. It is odorless and tasteless.

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

It is gradually affected by light.

Identification (1) Determine the absorption spectrum of a solution of Calcium Folate (1 in 100,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of a solution of Calcium Folate Reference Standard prepared in the same manner as the sample solution: both spectra exhibit similar intensities of absorption at the same wavelengths.

(2) Determine the infrared absorption spectrum of Calcium Folate, previously dried, as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of previously dried Calcium Folate Reference Standard: both spectra exhibit similar intensities of absorption at the same wave numbers.

(3) A solution of Calcium Folate (1 in 100) responds to the Qualitative Tests (2), (3) and (4) for calcium salt.

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Calcium Folate in 10 mL of water: the solution is clear and yellow.

(2) Heavy metals—Proceed with 0.40 g of Calcium Folate according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 50 ppm).

Water Weigh accurately about 0.2 g of Calcium Folate in a dried titration flask, and dissolve in 25 mL of acetic acid (100). Add 10.0 mL of Standard Water-Methanol Solution, titrate with Karl Fischer TS to the end point and perform the test: it is not more than 17.0%. Perform a blank determination, and make any necessary correction.

Assay Weigh accurately about 0.02 g of Calcium Folate, dissolve in the mobile phase to make exactly 100 mL, and use this solution as the sample solution. Separately, weigh

accurately about 0.0175 g of Calcium Folate Reference Standard, calculated on the anhydrous basis, dissolve in the mobile phase to make exactly 100 mL, and use this solution as the standard solution. Perform the test with 20 μ L each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions, and determine the peak areas, A_T and A_S , of folinate in each solution.

$$\begin{aligned} & \text{Amount (mg) of } C_{20}H_{21}CaN_7O_7 \\ &= \text{amount (mg) of Calcium Folate Reference} \\ & \quad \text{Standard, calculated on the anhydrous basis} \\ & \quad \times \frac{A_T}{A_S} \end{aligned}$$

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 254 nm).

Column: A stainless steel column about 4 mm in inside diameter and about 25 cm in length, packed with octadecylsilylated silica gel for liquid chromatography (5 to 10 μ m in particle diameter).

Column temperature: Room temperature.

Mobile phase: To 860 mL of water add 100 mL of acetonitrile and 15 mL of tetrabutylammonium hydroxide-methanol TS, adjust the pH to 7.5 with 2 mol/L sodium dihydrogenphosphate TS, and add water to make 1000 mL.

Flow rate: Adjust the flow rate so that the retention time of folinate is about 10 minutes.

Selection of column: Dissolve 0.0175 g of folic acid in 100 mL of the mobile phase, and to 5 mL of this solution add 20 mL of the standard solution. Proceed with 20 μ L of this solution under the above operating conditions, and calculate the resolution. Use a column giving elution of folinate and folic acid in this order with the resolution of these peaks being not less than 3.6.

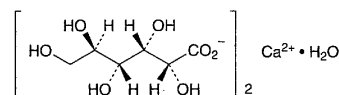
System repeatability: When the test is repeated 6 times with the standard solution under the above operating conditions, the relative standard deviation of each peak area of folinate is not more than 2.0%.

Containers and storage Containers—Tight containers.

Storage—Light-resistant.

Calcium Gluconate

グルコン酸カルシウム



$C_{12}H_{22}CaO_{14} \cdot H_2O$: 448.39

Monocalcium di-*D*-gluconate monohydrate [299-28-5]

Calcium Gluconate, when dried, contains not less than 99.0% and not more than 104.0% of $C_{12}H_{22}CaO_{14} \cdot H_2O$.

Description Calcium Gluconate occurs as a white, crystalline powder or granules. It is odorless and tasteless.

It is freely soluble in hot water, soluble in water, and prac-