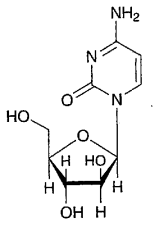
Cytarabine

シタラビン



$C_9H_{13}N_3O_5$: 243.22
4-Amino-1-β-D-arabinofuranosylpyrimidin-2(1*H*)-one
[*147-94-4*]

Cytarabine, when dried, contains not less than 98.5% of $C_9H_{13}N_3O_5$.

Description Cytarabine occurs as white crystals or crystalline powder.

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

Melting point: about 214°C (with decomposition).

Identification (1) To 1 mL of a solution of Cytarabine (1 in 1000) add 1 drop of bromine TS, allow to stand for 10 minutes, and expel the excess bromine under a current of air. To this solution add 1 mL of a solution of L-ascorbic acid (1 in 5000) and 1 mL of ninhydrin TS, and heat in a water bath for 30 minutes: a purple color develops.

(2) To 1 mL of a solution of Cytarabine (1 in 100) add 1 mL of orcin-ferric chloride TS, and heat in a water bath for 30 minutes: a green color develops.

Absorbance $E^{1\%}_{1cm}$ (282 nm): 530 – 570 (after drying, 2 mg, 0.1 mol/L hydrochloric acid TS, 200 mL).

Optical rotation $[\alpha]^{20}_D$: +154 – +160° (after drying, 0.1 g, water, 10 mL, 100 mm).

pH Dissolve 0.20 g of Cytarabine in 20 mL of water: the pH of this solution is between 6.5 and 8.0.

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

(2) Chloride—Perform the test with 1.0 g of Cytarabine. Prepare the control solution with 0.25 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.009%).

(3) Heavy metals—Proceed with 1.0 g of Cytarabine according to Method 1, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(4) Arsenic—Prepare the test solution with 1.0 g of Cytarabine according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).

(5) Related substances—Dissolve 0.10 g of Cytarabine in 10 mL of water, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add water to make exactly 200 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 with fluorescent indicator for thin-layer chromatography. Develop the plate with 1-butanol saturated with water to a distance of about 12 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution. Spray evenly acidic potassium permanganate TS on the plate: any spot other than the principal spot does not appear.

Loss on drying Not more than 1.0% (1 g, in vacuum, silica gel, 4 hours).

Residue on ignition Not more than 0.5% (1 g).

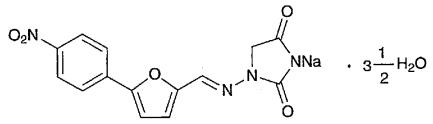
Assay Weigh accurately about 0.2 g of Cytarabine, previously dried, dissolve in 50 mL of acetic acid (100), and titrate with 0.05 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.05 mol/L perchloric acid VS
= 12.161 mg of $C_9H_{13}N_3O_5$

Containers and storage Containers—Tight containers.

Dantrolene Sodium

ダントロレンナトリウム



$C_{14}H_9N_4NaO_5.3\frac{1}{2}H_2O$: 399.29
Monosodium 3-[5-(4-nitrophenyl)furan-2-ylmethylene]amino-2,5-dioxo-1,3-imidazolidinate hemiheptahydrate
[*14663-23-1*, anhydride]

Dantrolene Sodium contains not less than 98.0% of $C_{14}H_9N_4NaO_5$, calculated on the anhydrous basis.

Description Dantrolene Sodium occurs as a yellowish orange to deep orange, crystalline powder.

It is soluble in propylene glycol, sparingly soluble in methanol, slightly soluble in ethanol (95), very slightly soluble in water and in acetic acid (100), and practically insoluble in acetone, in tetrahydrofuran and in diethyl ether.

Identification (1) Determine the absorption spectrum of a solution of Dantrolene Sodium in methanol (1 in 100,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.

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