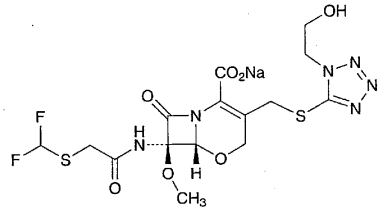
Each mL of 0.1 mol/L perchloric acid VS
= 40.64 mg of $C_{20}H_{17}F_3N_2O_4$

Containers and storage Containers—Tight containers.

Flomoxef Sodium

フロモキセフナトリウム



$C_{15}H_{17}F_2N_6NaO_7S_2$: 518.45
Monosodium (6*R*,7*R*)-7-(2-difluoromethylsulfanylacetylamino)-3-[1-(2-hydroxyethyl)-1*H*-tetrazol-5-ylsulfanylmethyl]-7-methoxy-8-oxo-5-oxa-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate [*92823-03-5*]

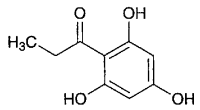
Flomoxef Sodium conforms to the requirements of Flomoxef Sodium in the Requirements for Antibiotic Products of Japan.

Description Flomoxef Sodium occurs as a white to light yellowish white powder or mass.

It is very soluble in water and in methanol, sparingly soluble in ethanol (99.5), and practically insoluble in diethyl ether.

Flopropione

フロプロピオン



$C_9H_{10}O_4$: 182.17
1-(2,4,6-Trihydroxyphenyl)propan-1-one [*2295-58-1*]

Flopropione contains not less than 98.0% of $C_9H_{10}O_4$, calculated on the anhydrous basis.

Description Flopropione occurs as a white to pale yellow-brown, crystalline powder. It is odorless, and has a bitter taste.

It is very soluble in *N,N*-dimethylformamide, freely soluble in methanol, in ethanol (99.5) and in diethyl ether, and practically insoluble in water.

Identification (1) To 1 mL of a solution of Flopropione in ethanol (99.5) (1 in 200) add 4 mL of water and 1 mL of iron (III) nitrate TS: a red-purple color develops.

(2) Determine the absorption spectrum of a solution of Flopropione in ethanol (99.5) (1 in 200,000) 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.

Melting point 177 - 181°C

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Flopropione in 10 mL of ethanol (99.5): the solution is clear, and has no more color than Matching Fluid H.

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

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

(4) Related substances—Dissolve 0.10 g of Flopropione in 10 mL of ethanol (99.5), and use this solution as the sample solution. Pipet 1 mL of the sample solution, add ethanol (99.5) 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 for thin-layer chromatography. Develop the plate with a mixture of hexane, ethanol (99.5) and acetic acid (100) (40:20:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly *p*-nitrobenzenediazonium TS for spraying on the plate, and dry in cold wind for about 5 minutes: the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Water Not more than 4.0% (0.5 g, direct titration).

Residue on ignition Not more than 0.10% (1 g).

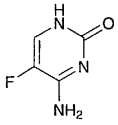
Assay Weigh accurately about 0.3 g of Flopropione, dissolve in 30 mL of *N,N*-dimethylformamide, and titrate with 0.1 mol/L tetramethylammonium hydroxide VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L tetramethylammonium hydroxide VS
= 18.218 mg of $C_9H_{10}O_4$

Containers and storage Containers—Tight containers. Storage—Light-resistant.

Flucytosine

フルシトシン



$C_4H_4FN_3O$: 129.09
4-Amino-5-fluoropyrimidin-2(1*H*)-one [*2022-85-7*]

Flucytosine, when dried, contains not less than 98.5% of $C_4H_4FN_3O$, and not less than 14.0% and not more than 15.5% of fluorine (F: 19.00).

Description Flucytosine occurs as a white, crystalline powder.

It is odorless.

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

It dissolves in 0.1 mol/L hydrochloric acid TS.

The pH of a solution of Flucytosine (1 in 100) is between 5.5 and 7.5.

It is slightly hygroscopic.

Melting point: about 295°C (with decomposition).

Identification (1) Add 0.2 mL of bromine TS to 5 mL of a solution of Flucytosine (1 in 500): a yellow-brown color of bromine TS is immediately discharged. Further add 2 mL of barium hydroxide TS: a purple precipitate is formed.

(2) Proceed with 0.1 g of Flucytosine as directed under the Oxygen Flask Combustion Method, using a mixture of 0.5 mL of 0.01 mol/L sodium hydroxide TS and 20 mL of water as the absorbing liquid. The solution responds to the Qualitative Tests (2) for fluoride.

(3) Determine the absorption spectrum of a solution of Flucytosine in 0.1 mol/L hydrochloric acid TS (1 in 125,000) 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.

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Flucytosine in 100 mL of water: the solution is clear and colorless.

(2) Chloride—Dissolve 1.0 g of Flucytosine in 80 mL of water by heating on a water bath. After cooling, to 40 mL of this solution add 6 mL of dilute nitric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 0.20 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.014%).

(3) Fluoride—Dissolve 0.10 g of Flucytosine in 10.0 mL of diluted 0.01 mol/L sodium hydroxide TS (1 in 20). Transfer 5.0 mL of this solution to a 20-mL volumetric flask, add 10 mL of a mixture of alizarin complexone TS, acetic acid-potassium acetate buffer solution, pH 4.3, and cerrous nitrate TS (1:1:1), and add water to make 20 mL. Allow the mixture to stand for 1 hour, and use this solution as the sample solution. Separately, transfer 4.0 mL of Standard Fluorine Solution to a 20-mL volumetric flask, add 5.0 mL of diluted 0.01 mol/L sodium hydroxide TS (1 in 20), add 10 mL of a mixture of alizarin complexone TS, acetic acid-potassium acetate buffer solution, pH 4.3, and cerrous nitrate TS (1:1:1). Proceed in the same manner as directed in the preparation of the sample solution, and use this solution as the standard solution. Transfer 5.0 mL of diluted 0.01 mol/L sodium hydroxide TS (1 in 20) to a 20-mL volumetric flask, proceed in the same manner as directed in the preparation of the standard solution, and use this solution as the blank solution. Determine the absorbances, A_T and A_S, of the sample solution and the standard solution at 600 nm, using the blank solution as the control as directed under Spectrophotometry: A_T is not larger than A_S (not more than 0.048%).

(4) Heavy metals—Proceed with 1.0 g of Flucytosine according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

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

(6) Related substances—Dissolve 0.050 g of Flucytosine in 5 mL of diluted methanol (1 in 2), and use this solution as the sample solution. Measure accurately 1 mL of this solution, add diluted methanol (1 in 2) to make exactly 25 mL. Measure accurately 1 mL of this solution, add diluted methanol (1 in 2) to make exactly 20 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 20 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 chromatogram with a mixture of ethyl acetate, methanol and water (5:3:2) to a distance of about 12 cm, air-dry the plate, and observe the spots 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.

Loss on drying Not more than 1.0% (1 g, 105°C, 4 hours).

Residue on ignition Not more than 0.10% (1 g).

Assay (1) Flucytosine—Weigh accurately about 0.2 g of Flucytosine, previously dried, dissolve in 40 mL of acetic acid (100), add 100 mL of acetic anhydride, and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination.

Each mL of 0.1 mol/L perchloric acid VS
= 12.909 mg of $C_4H_4FN_3O$

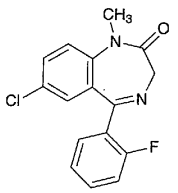
(2) Fluorine—Weigh accurately about 0.01 g of Flucytosine, previously dried, and proceed as directed in the determination of fluorine under the Oxygen Flask Combustion Method, using a mixture of 0.5 mL of 0.01 mol/L sodium hydroxide VS and 20 mL of water as the absorbing liquid.

Containers and storage Containers—Tight containers.

Storage—Light-resistant.

Fludiazepam

フルジアゼパム



$C_{16}H_{12}ClFN_2O$: 302.73

7-Chloro-5-(2-fluorophenyl)-1,3-dihydro-1-methyl-2*H*-1,4-benzodiazepin-2-one [*3900-31-0*]

Fludiazepam, when dried, contains not less than 99.0% of $C_{16}H_{12}ClFN_2O$.

Description Fludiazepam occurs as white to light yellow crystals or crystalline powder.

It is very soluble in chloroform, freely soluble in