mL of this solution, add chloroform 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 5 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 a mixture of 1-butanol, water and acetic acid (100) (3:1:1) 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.

Loss on drying Not more than 1.0% (1 g, reduced pressure, silica gel, 2 hours).

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

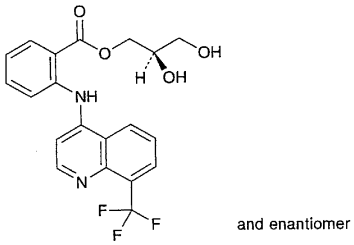
Assay Weigh accurately about 0.6 g of Flavoxate Hydrochloride, previously dried, add 10 mL of acetic acid (100) and 40 mL of acetonitrile to dissolve, add 50 mL of acetic anhydride, and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 42.79 mg of $C_{24}H_{25}NO_4.HCl$

Containers and storage Containers—Tight containers.

Floctafenine

フロクタフェニン



and enantiomer

$C_{20}H_{17}F_3N_2O_4$: 406.36
(*RS*)-2,3-Dihydroxypropyl 2-[8-(trifluoromethyl)-quinoline-4-ylamino]benzoate [*23779-99-9*]

Floctafenine, when dried, contains not less than 98.5% of $C_{20}H_{17}F_3N_2O_4$.

Description Floctafenine occurs as a white to pale yellowish white crystalline powder.

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

A solution of Floctafenine in 0.1 mol/L hydrochloric acid TS (1 in 100) shows no optical rotation.

Identification (1) Determine the absorption spectrum of a solution of Floctafenine in 0.1 mol/L hydrochloric acid TS (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 Floctafenine, previously dried, 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.

Melting point 176 - 180°C

Purity (1) Heavy metals—Proceed with 2.0 g of Floctafenine according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

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

(3) Related substances—Dissolve 0.020 g of Floctafenine in 50 mL of the mobile phase, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add the mobile phase to make exactly 100 mL, and use this solution as the standard solution. Perform the test with 20 μL each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions. Determine each peak area from both solutions by the automatic integration method: the total area of the peaks other than the peak of floctafenine from the sample solution is not larger than the peak area of floctafenine from the standard solution.

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 224 nm).

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

Column temperature: A constant temperature of about 25°C.

Mobile phase: Adjust the pH of a mixture of methanol, water and phosphoric acid (240:160:1) to 3.5 with sodium hydroxide TS.

Flow rate: Adjust the flow rate so that the retention time of floctafenine is about 6 minutes.

Selection of column: Dissolve 0.01 g of floctafenine and 0.05 g of ethyl parahydroxybenzoate in 250 mL of the mobile phase. Proceed with 20 μL of this solution according to the above operating conditions, and calculate the resolution. Use a column giving elution of floctafenine and ethyl parahydroxybenzoate in this order with the resolution between these peaks being not less than 7.

Detection sensitivity: Adjust the detection sensitivity so that the peak height of floctafenine from 20 μL of the standard solution is between 5 % and 15% of the full scale.

Time span of measurement: About four times as long as the retention time of floctafenine after the solvent peak.

Loss on drying Not more than 1.0% (1 g, 105°C, 2 hours).

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

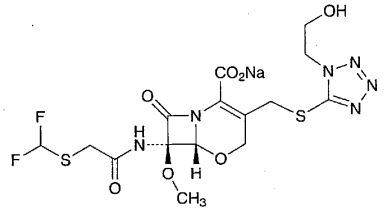
Assay Weigh accurately about 0.6 g of Floctafenine, previously dried, dissolve in 30 mL of acetic acid (100), and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

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*]

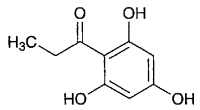
Flomoxef Sodium conforms to the requirements of Flomoxef Sodium in the Requirements for Antibiotic Products of Japan.

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).

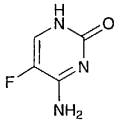
Assay Weigh accurately about 0.3 g of Flopropione, dissolve in 30 mL of *N,N*-dimethylformamide, and titrate with 0.1 mol/L tetramethylammonium hydroxide VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

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).