

bromine TS on a water bath for 5 minutes, concentrate to 5 mL, and cool. Perform the test using Apparatus B with this solution as the test solution (not more than 1.3 ppm).

(9) 5-Hydroxymethylfurfurals—Dissolve 5.0 g of Fructose in 100 mL of water, and read the absorbance at 284 nm as directed under the Ultraviolet-visible Spectrophotometry: the absorbance is not more than 0.32.

Loss on drying Not more than 0.5% (1 g, in vacuum, silica gel, 3 hours).

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

Assay Weigh accurately about 4 g of Fructose, previously dried, dissolve in 0.2 mL of ammonia TS and 80 mL of water, and after standing for 30 minutes add water to make exactly 100 mL, and determine the optical rotation, α_D , in a 100-mm cell at $20 \pm 1^\circ\text{C}$ as directed under the Optical Rotation Determination.

$$\text{Amount (mg) of } \text{C}_6\text{H}_{12}\text{O}_6 = |\alpha_D| \times 1087.0$$

Containers and storage Containers—Tight containers.

Fructose Injection

果糖注射液

Fructose Injection is an aqueous solution for injection. It contains not less than 95% and not more than 105% of the labeled amount of fructose ($\text{C}_6\text{H}_{12}\text{O}_6$; 180.16).

Method of preparation Prepare as directed under Injections, with Fructose. No preservative is added.

Description Fructose Injection is a colorless to pale yellow, clear liquid. It has a sweet taste.

Identification (1) Take a volume of Fructose Injection, equivalent to 1 g of Fructose according to the labeled amount, dilute with water or concentrate on a water bath to 20 mL, if necessary, and use this solution as the sample solution. Add 2 to 3 drops of the sample solution to 5 mL of boiling Fehling's TS: a red precipitate is produced.

(2) To 10 mL of the sample solution obtained in (1) add 0.1 g of resorcinol and 1 mL of hydrochloric acid, and warm in a water bath for 3 minutes: a red color develops.

pH 3.0–6.5 In the case where the labeled concentration of the injection exceeds 5%, dilute to 5% with water before the test.

Purity (1) Heavy metals—Take a volume of Fructose Injection, equivalent to 5.0 g of Fructose, according to the labeled amount, and evaporate on a water bath to dryness. With the residue, proceed according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution.

(2) Arsenic—Take a volume of Fructose Injection, equivalent to 1.5 g of Fructose, according to the labeled amount, dilute with water or concentrate on a water bath to 5 mL, if necessary, and add 5 mL of dilute sulfuric acid and 1 mL of bromine TS. Proceed as directed in the purity (8) under Fructose.

Residue on ignition Measure exactly a volume of Fructose Injection, equivalent to about 2.0 g of Fructose according to the labeled amount, evaporate on a water bath to dryness, and perform the test: the residue weighs not more than 2.0 mg.

Pyrogen Perform the test with Fructose Injection stored in a container in a volume exceeding 10 mL: it meets the requirements of the Pyrogen Test.

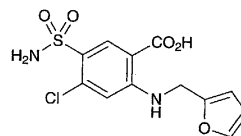
Assay Measure exactly a volume of Fructose Injection equivalent to about 4 g of fructose ($\text{C}_6\text{H}_{12}\text{O}_6$), add 0.2 mL of ammonia TS, dilute with water to make exactly 100 mL, shake well, and after allowing to stand for 30 minutes, determine the optical rotation, α_D , in a 100-mm cell at $20 \pm 1^\circ\text{C}$ as directed under the Optical Rotation Determination.

$$\text{Amount (mg) of fructose (C}_6\text{H}_{12}\text{O}_6) = |\alpha_D| \times 1087.0$$

Containers and storage Containers—Hermetic containers. Plastic containers for aqueous injections may be used.

Furosemide

フロセミド



$\text{C}_{12}\text{H}_{11}\text{ClN}_2\text{O}_5\text{S}$: 330.74

4-Chloro-2-[(furan-2-ylmethyl)amino]-5-sulfamoylbenzoic acid [54-31-9]

Furosemide, when dried, contains not less than 98.0% of $\text{C}_{12}\text{H}_{11}\text{ClN}_2\text{O}_5\text{S}$.

Description Furosemide occurs as white crystals or crystalline powder. It is odorless.

It is freely soluble in *N,N*-dimethylformamide, soluble in methanol and in acetone, sparingly soluble in ethanol (95), slightly soluble in diethyl ether, and practically insoluble in water.

It dissolves in sodium hydroxide TS.

It is gradually colored by light.

Melting point: about 205°C (with decomposition).

Identification (1) Dissolve 0.025 g of Furosemide in 10 mL of methanol. To 1 mL of this solution add 10 mL of 2 mol/L hydrochloric acid TS. Heat the solution on a water bath under a reflux condenser for 15 minutes, cool, and add 18 mL of sodium hydroxide TS to make weakly acidic: this solution responds to the Qualitative Tests for primary aromatic amines. A red to red-purple color is produced.

(2) Perform the Flame Coloration Test (2): A green color appears.

(3) Fuse cautiously a mixture of 0.1 g of Furosemide and 0.5 g of sodium carbonate decahydrate: the gas evolved changes moistened red litmus paper to blue. Cool the fused matter, crush it with a glass rod, add 10 mL of water, stir, and filter. To the filtrate add 4 drops of hydrogen peroxide (30), 10 mL of diluted hydrochloric acid (1 in 5) and 4 to 5

drops of barium chloride TS: a white precipitate is produced.

(4) Determine the absorption spectrum of a solution of Furosemide in dilute sodium hydroxide TS (1 in 25,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum 1: both spectra exhibit similar intensities of absorption at the same wavelengths. Separately, determine the absorption spectrum of a solution of Furosemide in methanol (1 in 250,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum 2: both spectra exhibit similar intensities of absorption at the same wavelengths.

Purity (1) Clarity and color of solution—Dissolve 0.10 g of Furosemide in 10 mL of ethanol (95) by warming, and allow to cool to room temperature: the solution is colorless and clear. Dissolve 0.5 g of Furosemide in 10 mL of a solution of sodium hydroxide (1 in 50): the solution is also colorless and clear.

(2) Chloride—Dissolve 0.5 g of Furosemide in 30 mL of dilute sodium hydroxide TS, add 1 mL of nitric acid, and filter. To 10 mL of the filtrate add 6 mL of dilute nitric acid and water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution with 0.25 mL of 0.01 mol/L hydrochloric acid VS, 6 mL of dilute nitric acid and water to make 50 mL (not more than 0.055%).

(3) Sulfate—Dissolve 0.20 g of Furosemide in 10 mL of dilute sodium hydroxide TS, add 1 mL of nitric acid, and filter. Add 2 mL of barium chloride TS, and allow to stand for 10 minutes: no turbidity is produced.

(4) Heavy metals—Proceed with 2.0 g of Furosemide 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).

(5) Primary aromatic amines—Dissolve 0.080 g of Furosemide in acetone to make exactly 100 mL. Measure 1.0 mL of the solution, add 3 mL of water, cool with ice, add 3.0 mL of dilute hydrochloric acid and 0.15 mL of sodium nitrite TS, shake, and allow to stand for 1 minute. Shake well this solution with 1.0 mL of ammonium amidosulfate TS, allow to stand for 3 minutes, then add 1.0 mL of *N*-(1-naphthyl)-*N'*-diethylethylenediamine oxalate TS, shake well, and allow to stand for 5 minutes. Determine the absorbance of this solution at 530 nm as directed under the Ultraviolet-visible Spectrophotometry, using a solution, prepared with 1.0 mL of acetone in the same manner, as the blank: the absorbance is not more than 0.10.

Loss on drying Not more than 0.5% (1 g, 105°C, 4 hours).

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

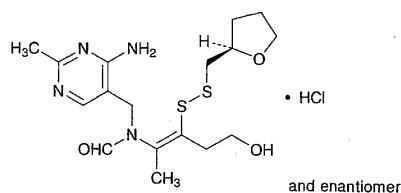
Assay Weigh accurately about 0.5 g of Furosemide, previously dried, dissolve in 50 mL of *N,N*-dimethylformamide, and titrate with 0.1 mol/L sodium hydroxide VS until the color of the solution changes from yellow to blue (indicator: 3 drops of bromothymol blue TS). Perform a blank determination with a mixture of 50 mL of *N,N*-dimethylformamide and 15 mL of water.

Each mL of 0.1 mol/L sodium hydroxide VS
= 33.075 mg of $C_{12}H_{11}ClN_2O_5S$

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

Fursultiamine Hydrochloride

塩酸フルスルチアミン



$C_{17}H_{26}N_4O_3S_2 \cdot HCl$: 435.00

N-(4-Amino-2-methylpyrimidin-5-ylmethyl)-*N*-{4-hydroxy-1-methyl-2-[(*RS*)-tetrahydrofuran-2-ylmethyl]disulfanyl}-but-1-en-1-yl}formamide monohydrochloride
[804-30-8, Fursultiamine]

Fursultiamine Hydrochloride contains not less than 98.5% of $C_{17}H_{26}N_4O_3S_2 \cdot HCl$, calculated on the dried basis.

Description Fursultiamine Hydrochloride occurs as white crystals or crystalline powder. It is odorless or has a characteristic odor, and has a bitter taste.

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

Identification (1) Dissolve 5 mg of Fursultiamine Hydrochloride in 6 mL of 0.1 mol/L hydrochloric acid TS, add 0.1 g of zinc powder, allow to stand for several minutes, and filter. To 3 mL of the filtrate, add 3 mL of sodium hydroxide TS and 0.5 mL of potassium hexacyanoferrate (III) TS, then add 5 mL of 2-methyl-1-propanol, shake vigorously for 2 minutes, allow to stand to separate the 2-methyl-1-propanol layer, and examine under ultraviolet light (main wavelength: 365 nm): the 2-methyl-1-propanol layer shows a blue-purple fluorescence. The fluorescence disappears by acidifying, and appears again by alkalifying.

(2) Determine the infrared absorption spectrum of a solution of Fursultiamine Hydrochloride, previously dried in a desiccator (in vacuum, phosphorus (V) oxide) for 24 hours, as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum, or with the spectrum of Fursultiamine Hydrochloride Reference Standard, previously dried in a desiccator (in vacuum, phosphorus (V) oxide) for 24 hours: both spectra exhibit similar intensities of absorption at the same wave numbers. If any differences appear, dissolve the Fursultiamine Hydrochloride in water, evaporate the water, and dry the residue in a desiccator (in vacuum, phosphorus (V) oxide) for 24 hours, and repeat the test.

(3) A solution of Fursultiamine Hydrochloride (1 in 50) responds to the Qualitative Tests (2) for chloride.

Purity (1) Clarity of solution—Dissolve 1.0 g of Fursultiamine Hydrochloride in 20 mL of water: the solution is clear and colorless.

(2) Sulfate—Proceed with 1.5 g of Fursultiamine Hydrochloride, and perform the test. Prepare the control solution with 0.35 mL of 0.005 mol/L sulfuric acid VS (not more than 0.011%).

(3) Heavy metals—Proceed with 1.0 g of Fursultiamine