tion standard solution, respectively.

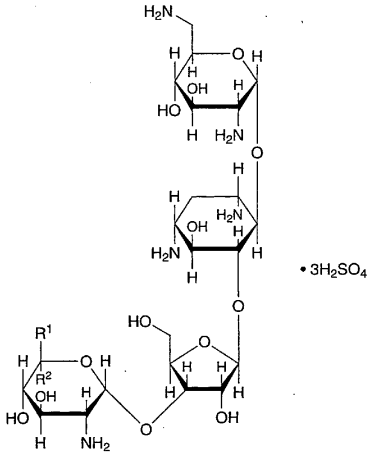
(5) Sample solution—Weigh accurately an amount of Fosfomycin Sodium equivalent to about 0.02 g (potency), and dissolve in 0.05 mol/L Tris buffer solution, pH 7.0 to make exactly 50 mL. To exactly a suitable amount of this solution add 0.05 mol/L Tris buffer solution, pH 7.0 to make solutions so that each mL contains 10 μg (potency) and 5 μg (potency), and use these solutions as the high concentration sample solution and the low concentration sample solution, respectively.

Containers and storage Containers—Hermetic containers.

Fradiomycin Sulfate

Neomycin Sulfate

硫酸フラジオマイシン



Fradiomycin B: R^1=H R^2=CH_2NH_2

Fradiomycin C: R^1=CH_2NH_2 R_2=H

$C_{23}H_{46}N_6O_{13}.3H_2SO_4$: 908.88

Fradiomycin Sulfate B

O-2,6-Diamino-2,6-dideoxy-α-D-glucopyranosyl-(1→4)-*O*-[*O*-2,6-diamino-2,6-dideoxy-α-D-glucopyranosyl-(1→3)-β-D-ribofuranosyl-(1→5)]-2-deoxy-D-streptamine trisulfate [*119-04-0*]

Fradiomycin Sulfate C

O-2,6-Diamino-2,6-dideoxy-α-D-glucopyranosyl-(1→4)-*O*-[*O*-2,6-diamino-2,6-dideoxy-β-L-idopyranosyl-(1→3)-β-D-ribofuranosyl-(1→5)]-2-deoxy-D-streptamine trisulfate [*66-86-4*] [*1405-10-3*, Neomycin Sulfate]

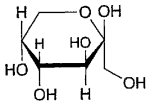
Fradiomycin Sulfate conforms to the requirements of Fradiomycin Sulfate in the Requirements for Antibiotic Products of Japan.

Description Fradiomycin Sulfate occurs as a white to light yellow powder.

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

Fructose

果糖



$C_6H_{12}O_6$: 180.16

β-D-Fructopyranose [*57-48-7*]

Fructose, when dried, contains not less than 98.0% of $C_6H_{12}O_6$.

Description Fructose occurs as colorless to white crystals or crystalline powder. It is odorless and has a sweet taste.

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

It is hygroscopic.

Identification (1) Add 2 to 3 drops of a solution of Fructose (1 in 20) to 5 mL of boiling Fehling's TS: a red precipitate is produced.

(2) Determine the infrared absorption spectrum of Fructose as directed in the paste 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.

pH Dissolve 4.0 g of Fructose in 20 mL of water: the pH of the solution is between 4.0 and 6.5.

Purity (1) Clarity and color of solution—Dissolve 25.0 g of Fructose in 50 mL of water: the solution is clear and has no more color than the following control solution.

Control solution: To a mixture of 1.0 mL of Cobaltous Chloride Stock CS, 3.0 mL of Ferric Chloride Stock CS and 2.0 mL of Cupric Sulfate Stock CS, and add water to make 10.0 mL. To 3.0 mL of the solution add water to make 50 mL.

(2) Acid—Dissolve 5.0 g of Fructose in 50 mL of freshly boiled and cooled water, and add 3 drops of phenolphthalein TS and 0.60 mL of 0.01 mol/L sodium hydroxide VS: a red color develops.

(3) Chloride—Perform the test with 2.0 g of Fructose. Prepare the control solution with 1.0 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.018%).

(4) Sulfate—Perform the test with 2.0 g of Fructose. Prepare the control solution with 1.0 mL of 0.005 mol/L sulfuric acid VS (not more than 0.024%).

(5) Sulfite—Dissolve 0.5 g of Fructose in 5 mL of water, and add 0.25 mL of 0.02 mol/L iodine: the color of the solution is yellow.

(6) Heavy metals—Proceed with 5.0 g of Fructose according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 4 ppm).

(7) Calcium—Dissolve 0.5 g of Fructose in 5 mL of water, add 2 to 3 drops of ammonia TS and 1 mL of ammonium oxalate TS, and allow to stand for 1 minute: the solution is clear.

(8) Arsenic—Dissolve 1.5 g of Fructose in 5 mL of water, heat with 5 mL of dilute sulfuric acid and 1 mL of

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 ± 1°C as directed under the Optical Rotation Determination.

Amount (mg) of $C_6H_{12}O_6 = |\alpha_D| \times 1087.0$

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 ($C_6H_{12}O_6$: 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.

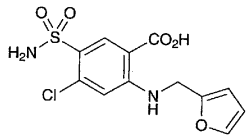
Assay Measure exactly a volume of Fructose Injection equivalent to about 4 g of fructose ($C_6H_{12}O_6$), add 0.2 mL of ammonia TS, dilute with water to make exactly 100 mL, shake well, and after allowing to stand for 30 minutes, determine the optical rotation, α_D, in a 100-mm cell at 20 ± 1°C as directed under the Optical Rotation Determination.

Amount (mg) of fructose ($C_6H_{12}O_6$) = $|\alpha_D| \times 1087.0$

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

Furosemide

フロセミド



$C_{12}H_{11}ClN_2O_5S$: 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 $C_{12}H_{11}ClN_2O_5S$.

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