

Identification Weigh a quantity of powdered Isosorbide Dinitrate Tablets, equivalent to 0.1 g of Isosorbide Dinitrate according to the labeled amount, add 50 mL of diethyl ether, shake well, and filter. Measure 5 mL of the filtrate, evaporate to dryness cautiously, add 1 mL of water to the residue, and dissolve by adding 2 mL of sulfuric acid cautiously. After cooling, superimpose 3 mL of iron (II) sulfate TS, and allow to stand for 5 to 10 minutes: a brown ring is produced at the zone of contact.

Purity Free nitrate ion—Weigh accurately a quantity of powdered Isosorbide Dinitrate Tablets, equivalent to 0.05 g of Isosorbide Dinitrate according to the labeled amount, transfer to a separator, add 30 mL of toluene, shake thoroughly, extract with three 20-mL portions of water, and proceed as directed in Purity (3) under Isosorbide Dinitrate.

Disintegration test Isosorbide Dinitrate Tablets meet the requirements of the Disintegration Test. For sublingual tablets, the time limit of the test is 2 minutes, and omit the use of the disk.

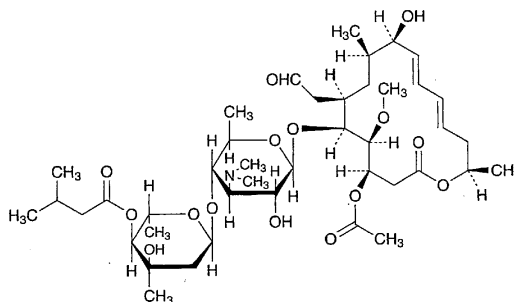
Assay Weigh accurately and powder not less than 20 Isosorbide Dinitrate Tablets. Weigh accurately a portion of the powder, equivalent to about 5 mg of isosorbide dinitrate ($C_6H_8N_2O_8$), add exactly 50 mL of acetic acid (100), shake for 15 minutes, filter, and use this filtrate as the sample solution. Separately, weigh accurately about 0.09 g of potassium nitrate, previously dried at 105°C for 4 hours, dissolve in 5 mL of water, and add acetic acid (100) to make exactly 100 mL. Measure exactly 10 mL of this solution, add acetic acid (100) to make exactly 100 mL, and use this solution as the standard solution. Measure exactly 2 mL each of the sample solution and the standard solution, add exactly 2.5 mL of salicylic acid TS to each, shake well, allow to stand for 15 minutes, and add 10 mL of water. Make them alkaline with about 12 mL of a solution of sodium hydroxide (2 in 5) while cooling in an ice bath, and add water to make exactly 50 mL. Perform the test with these solutions as directed under the Ultraviolet-visible Spectrophotometry, using a solution, prepared with 2 mL of glacial acetic in the same manner, as the blank. Determine the absorbances, A_T and A_S , of the subsequent solutions of the sample solution and the standard solution at 412 nm, respectively.

$$\begin{aligned} \text{Amount (mg) of isosorbide dinitrate (C}_6\text{H}_8\text{N}_2\text{O}_8\text{)} \\ &= \text{amount (mg) of potassium nitrate} \\ &\times \frac{A_T}{A_S} \times \frac{1}{20} \times 1.1679 \end{aligned}$$

Containers and storage Containers—Tight containers.

Josamycin

ジョサマイシン



$C_{42}H_{69}NO_{15}$: 827.99

(3*R*,4*R*,5*S*,6*R*,8*R*,9*R*,10*E*,12*E*,15*R*)-3-Acetoxy-5-[*O*-2,6-dideoxy-4-*O*-(3-methylbutanoyl)-3-*C*-methyl- α -*L*-ribo-hexopyranosyl-(1 \rightarrow 4)-3,6-dideoxy-3-dimethylamino- β -*D*-glucopyranosyloxy]-6-formylmethyl-9-hydroxy-4-methoxy-8-methylhexadeca-10,12-dien-15-olide [16846-24-5]

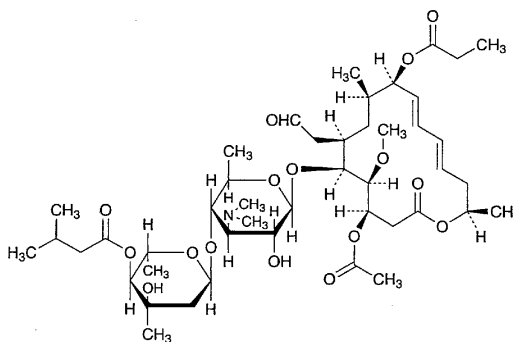
Josamycin conforms to the requirements of Josamycin in the Requirements for Antibiotic Products of Japan.

Description Josamycin occurs as a white to yellowish white powder. It has a bitter taste.

It is very soluble in methanol, in ethanol (95) and in diethyl ether, and very slightly soluble in water.

Josamycin Propionate

プロピオン酸ジョサマイシン



$C_{45}H_{73}NO_{16}$: 884.06

(3*R*,4*R*,5*S*,6*R*,8*R*,9*R*,10*E*,12*E*,15*R*)-3-Acetoxy-5-[*O*-2,6-dideoxy-4-*O*-(3-methylbutanoyl)-3-*C*-methyl- α -*L*-ribo-hexopyranosyl-(1 \rightarrow 4)-3,6-dideoxy-3-dimethylamino- β -*D*-glucopyranosyloxy]-6-formylmethyl-4-methoxy-8-methyl-9-propionyloxyhexadeca-10,12-dien-15-olide [16846-24-5, Josamycin]

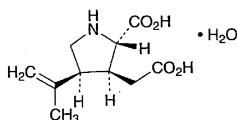
Josamycin Propionate conforms to the requirements of Josamycin Propionate in Requirements for Antibiotic Products of Japan.

Description Josamycin Propionate occurs as a white to light yellowish white crystalline powder.

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

Kainic Acid

カイニン酸



$C_{10}H_{15}NO_4 \cdot H_2O$: 231.25
(2*S*,3*S*,4*S*)-3-(Carboxymethyl)-4-isopropenylpyrrolidine-2-carboxylic acid monohydrate [487-79-6, anhydride]

Kainic Acid, when dried, contains not less than 99.0% of $C_{10}H_{15}NO_4$: 213.23.

Description Kainic Acid occurs as white crystals or crystalline powder. It is odorless, and has an acid taste.

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

It dissolves in dilute hydrochloric acid and in sodium hydroxide TS.

The pH of its solution (1 in 100) is between 2.8 and 3.5. Melting point: about 252°C (with decomposition).

Identification (1) To 5 mL of a solution of Kainic Acid (1 in 5000) add 1 mL of ninhydrin TS, and warm in a water bath at a temperature between 60°C and 70°C for 5 minutes: a yellow color is produced.

(2) Dissolve 0.05 g of Kainic Acid in 5 mL of acetic acid (100), and add 0.5 mL of bromine TS: the color of bromine disappears immediately.

Optical rotation $[\alpha]_D^{20}$: -13 - -17° (0.5 g, water, 50 mL, 200 mm).

Purity (1) Clarity and color of solution—Dissolve 0.10 g of Kainic Acid in 10 mL of water: the solution is clear and colorless.

(2) Chloride—Take 0.5 g of Kainic Acid in a platinum crucible, dissolve in 5 mL of sodium carbonate TS, and evaporate on a water bath to dryness. Heat the crucible slowly at first, and then ignite until the sample is almost incinerated. After cooling, add 12 mL of dilute nitric acid to the residue, dissolve by warming, and filter. Wash the residue with 15 mL of water, combine the washings and the filtrate, and add water to make 50 mL. Perform the test using this solution as the test solution.

Control solution: Add 5 mL of sodium carbonate TS to 0.30 mL of 0.01 mol/L hydrochloric acid VS, and proceed as directed above (not more than 0.021%).

(3) Sulfate—Dissolve 0.5 g of Kainic Acid in 40 mL of water by warming. Cool, add 1 mL of dilute hydrochloric acid and water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution with 0.30 mL of 0.005 mol/L sulfuric acid VS (not more than 0.028%).

(4) Ammonium—Take 0.25 g of Kainic Acid, and perform the test. Prepare the control solution with 5.0 mL of Standard Ammonium Solution (not more than 0.02%).

(5) Heavy metals—Proceed with 1.0 g of Kainic Acid 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).

(6) Arsenic—Dissolve 1.0 g of Kainic Acid in 5 mL of dilute hydrochloric acid, and perform the test with this solution as the test solution using Apparatus B (not more than 2 ppm).

(7) Amino acid and other imino acid—Dissolve 0.10 g of Kainic Acid in 10 mL of water, and use this solution as the sample solution. Pipet 2 mL of this solution, and add water to make exactly 100 mL. Pipet 1 mL of this solution, add water to make exactly 20 mL, and use this solution as the standard solution. Perform the test as directed under the Thin-layer Chromatography with these solutions. Spot 10 μ L each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with the supernatant liquid of a mixture of water, 1-butanol and acetic acid (100) (5:4:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly a solution of ninhydrin in acetone (1 in 50) on the plate, and dry the plate at 80°C for 5 minutes: 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 6.5 - 8.5% (1 g, 105°C, 4 hours).

Residue on ignition Not more than 0.1% (0.5 g).

Assay Weigh accurately about 0.4 g of Kainic Acid, previously dried, and dissolve in 50 mL of warm water, cool and titrate with 0.1 mol/L sodium hydroxide VS (indicator: 10 drops of bromothymol blue TS).

Each mL of 0.1 mol/L sodium hydroxide VS
= 21.323 mg of $C_{10}H_{15}NO_4$

Containers and storage Containers—Tight containers.

Kallidinogenase

カリジノゲナーゼ

[9001-01-8]

Kallidinogenase is an enzyme obtained from healthy porcine pancreas, and has kinin-releasing activity based on cleavage of kininogen. It contains not less than 25 Kallidinogenase Units per mg. Usually, it is diluted with Lactose or the like.

Kallidinogenase contains not less than 90% and not more than 110% of the labeled Units.

Description Kallidinogenase occurs as a white to light brown powder. It is odorless or has a faint, characteristic odor.

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

The pH of a solution of Kallidinogenase (1 in 300) is between 5.5 and 7.5.