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.

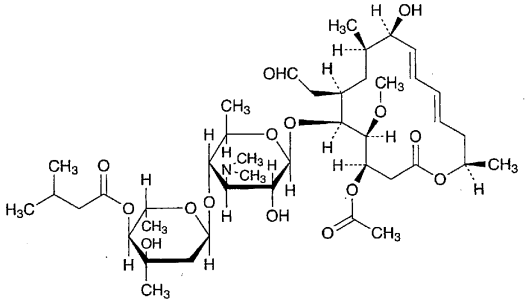
Assay Weigh accurately and powder not less than 20 Isosorbide Dinitrate Tablets. Weigh accurately a portion of the powder, equivalent to about 5 mg of isosorbide dinitrate ($C_6H_8N_2O_8$), add exactly 50 mL of acetic acid (100), shake for 15 minutes, filter, and use this filtrate as the sample solution. 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.

$$\text{Amount (mg) of isosorbide dinitrate } (C_6H_8N_2O_8) = \text{amount (mg) of potassium nitrate} \times \frac{A_T}{A_S} \times \frac{1}{20} \times 1.1679$$

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→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*]

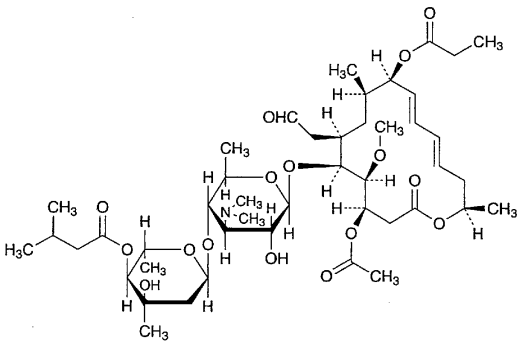
Josamycin conforms to the requirements of Josamycin in the Requirements for Antibiotic Products of Japan.

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→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.