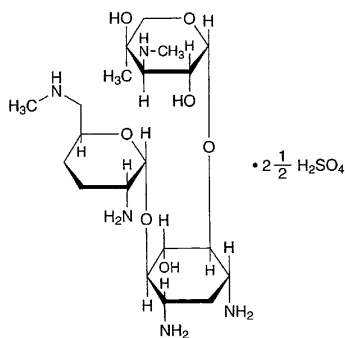


Micronomicin Sulfate

硫酸マイクロマイシン



$C_{20}H_{41}N_5O_7 \cdot 2\frac{1}{2}H_2SO_4$: 708.77

O-2-Amino-2,3,4,6-tetra-deoxy-6-methylamino- α -D-erythro-hexopyranosyl-(1 \rightarrow 4)-*O*-[3-deoxy-4-*C*-methyl-3-methylamino- β -L-arabinopyranosyl-(1 \rightarrow 6)]-2-deoxy-D-streptamine hemiheptasulfate
[52093-21-7, Micronomicin]

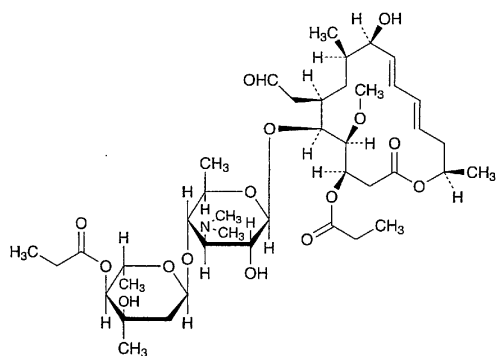
Micronomicin Sulfate conforms to the requirements of Micronomicin Sulfate in the Requirements for Antibiotic Products of Japan.

Description Micronomicin Sulfate occurs as a white to light yellowish white powder.

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

Midecamycin

ミデカマイシン



$C_{41}H_{67}NO_{15}$: 813.97

(3*R*,4*R*,5*S*,6*R*,8*R*,9*R*,10*E*,12*E*,15*R*)-5-[*O*-2,6-Dideoxy-3-*C*-methyl-4-*O*-propionyl- α -L-ribo-hexopyranosyl-(1 \rightarrow 4)-3,6-dideoxy-3-dimethylamino- β -D-glucopyranosyloxy]-6-formylmethyl-9-hydroxy-4-methoxy-8-methyl-3-propionyloxyhexadeca-10,12-dien-15-olide [35457-80-8]

Midecamycin contains not less than 900 μ g (potency) per mg, calculated on the dried basis. The potency

of Midecamycin is expressed as mass (potency) of midecamycin ($C_{41}H_{67}NO_{15}$).

Description Midecamycin occurs as a white crystalline powder.

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

Identification (1) Determine the absorption spectrum of a solution of Midecamycin in methanol (1 in 50,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of a solution of Midecamycin Reference Standard prepared in the same manner as the sample solution: both spectra exhibit similar intensities of absorption at the same wavelength.

(2) Determine the infrared absorption spectrum of Midecamycin as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of Midecamycin Reference Standard: both spectra exhibit similar intensities of absorption at the same wave numbers.

Melting point 153 – 158°C

Purity Heavy metals—Proceed with 1.0 g of Midecamycin according to Method 2, and perform the test. Prepare the control solution with 3.0 mL of Standard Lead Solution (not more than 30 ppm).

Loss on drying Not more than 2.0% (1.0 g, in vacuum not exceeding 0.67 kPa, 60°C, 3 hours).

Residue on ignition Not more than 0.2% (1 g).

Assay Perform the test according to the Cylinder-plate method as directed under the Microbial Assay for Antibiotics according to the following conditions.

(1) Test organism—*Bacillus subtilis* ATCC 6633

(2) Culture medium—Use the medium i in 1) Medium for test organism [5] under (1) Agar media for seed and base layer.

(3) Standard solution—Weigh accurately an amount of Midecamycin Reference Standard, previously dried, equivalent to about 0.02 g (potency), dissolve in 10 mL of methanol, add water to make exactly 50 mL, and use this solution as the standard stock solution. Keep the standard stock solution at 5°C or below and use within 7 days. Take exactly a suitable amount of the standard stock solution before use, add 0.1 mol/L phosphate buffer solution, pH 8.0 to make solutions so that each mL contains 20 μ g (potency) and 5 μ g (potency), and use these solutions as the high concentration standard solution and the low concentration standard solution, respectively.

(4) Sample solution—Weigh accurately an amount of Midecamycin, previously dried, equivalent to about 0.02 g (potency), dissolve in 10 mL of methanol, and add water to make exactly 50 mL. Take exactly a suitable amount of the solution, add 0.1 mol/L phosphate buffer solution, pH 8.0 to make solutions so that each mL contains 20 μ g (potency) and 5 μ g (potency), and use these solutions as the high concentration sample solution and the low concentration sample solution, respectively.

Containers and storage Containers—Tight containers.