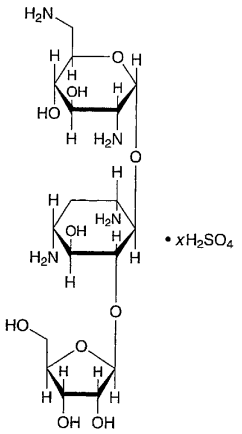
Ribostamycin Sulfate

硫酸リボスタマイシン



$C_{17}H_{34}N_4O_{10}.xH_2SO_4$
O-2,6-Diamino-2,6-dideoxy-α-D-glucopyranosyl-(1→4)-*O*-[β-D-ribofuranosyl-(1→5)]-2-deoxy-D-streptamine sulfate [*53797-35-6*]

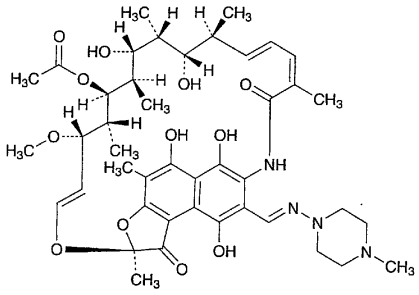
Ribostamycin Sulfate conforms to the requirements of Ribostamycin Sulfate in the Requirements for Antibiotic Products of Japan.

Description Ribostamycin Sulfate occurs as a white to yellowish white powder.

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

Rifampicin

リファンピシン



$C_{43}H_{58}N_4O_{12}$: 822.94
(2*S*,12*Z*,14*E*,16*S*,17*S*,18*R*,19*R*,20*R*,21*S*,22*R*,23*S*,24*E*)-1,2-Dihydro-5,6,9,17,19-pentahydroxy-23-methoxy-2,4,12,16,18,20,22-heptamethyl-8-(4-methylpiperazin-1-yliminomethyl)-1,11-dioxo-2,7-(epoxypentadeca[1,11,13]-trienimino)naphtho[2,1-*b*]furan-21-yl acetate [*13292-46-1*]

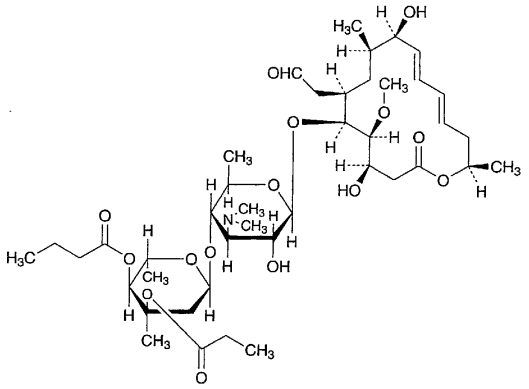
Rifampicin conforms to the requirements of Rifampicin in the Requirements for Antibiotic Products of Japan.

Description Rifampicin occurs as an orange-red to red-brown crystals or crystalline powder.

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

Rokitamycin

ロキタマイシン



$C_{42}H_{69}NO_{15}$: 827.99
(3*R*,4*S*,5*S*,6*R*,8*R*,9*R*,10*E*,12*E*,15*R*)-5-[*O*-(4-*O*-Butyryl-2,6-dideoxy-3-*C*-methyl-3-*O*-propionyl-α-L-*ribo*-hexopyranosyl)-(1→4)-3,6-dideoxy-3-dimethylamino-β-D-glucopyranosyloxy]-6-formylmethyl-3,9-dihydroxy-4-methoxy-8-methylhexadeca-10,12-dien-15-olide [*74014-51-0*]

Rokitamycin contains not less than 900 μg (potency) per mg, calculated on the anhydrous basis. The potency of Rokitamycin is expressed as mass (potency) of rokitamycin ($C_{42}H_{69}NO_{15}$).

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

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

Identification **(1)** Determine the absorption spectrum of a solution of Rokitamycin 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 Rokitamycin 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 Rokitamycin as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of Rokitamycin Reference Standard: both spectra exhibit similar intensities of absorption at the same wave numbers.

(3) Determine the spectrum of a solution of Rokitamycin in deuterated chloroform for nuclear magnetic resonance spectroscopy (1 in 20), using tetramethylsilane for nuclear magnetic resonance spectroscopy as an internal reference compound, as directed under the Nuclear Magnetic Resonance Spectroscopy (^1H): it exhibits single signals A,

B, C and D at around δ 1.4 ppm, at around δ 2.5 ppm, at around δ 3.5 ppm and at around δ 9.8 ppm, respectively. The ratio of integrated intensity of these signals, A:B:C:D, is about 3:6:3:1.

Purity Heavy metals—Proceed with 2.0 g of Rokitamycin 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).

Water Not more than 3.0% (0.2 g, volumetric titration, direct titration).

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—*Micrococcus luteus* ATCC 9341

(2) Culture medium—Use the medium i in 3) Medium for other organisms under (1) Agar media for seed and base layer. Adjust the pH of the medium so that it will be 7.8 to 8.0 after sterilization.

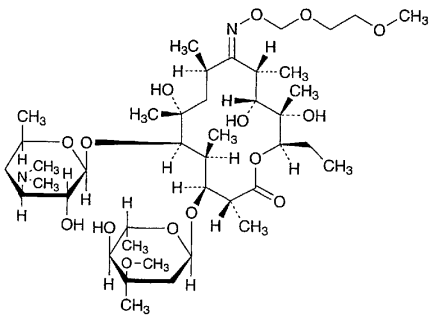
(3) Standard solution—Weigh accurately an amount of Rokitamycin Reference Standard equivalent to about 0.04 g (potency), dissolve in 50 mL of methanol, add 0.1 mol/L phosphate buffer solution, pH 4.5 to make exactly 100 mL, and use this solution as the standard stock solution. Keep the standard stock solution at 5°C or below and use within 10 days. Take exactly a suitable amount of the standard stock solution before use, add 0.1 mol/L phosphate buffer solution, pH 8.0 containing 0.01% of polysorbate 80 to make solutions so that each mL contains 2 μg (potency) and 0.5 μg (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 Rokitamycin equivalent to about 0.04 g (potency), dissolve in 50 mL of methanol, and add 0.1 mol/L phosphate buffer solution, pH 4.5 to make exactly 100 mL. Take exactly a suitable amount of the solution, add 0.1 mol/L phosphate buffer solution, pH 8.0 containing 0.01% of polysorbate 80 to make solutions so that each mL contains 2 μg (potency) and 0.5 μg (potency), and use these solutions as the high concentration sample solution and the low concentration sample solution, respectively.

Containers and storage Containers—Tight containers.

Roxithromycin

ロキシスロマイシン



$C_{41}H_{76}N_2O_{15}$: 837.05

(2*R*,3*S*,4*S*,5*R*,6*R*,8*R*,10*R*,11*R*,12*S*,13*R*)-5-(3,4,6-Trideoxy-3-dimethylamino-β-D-*xylo*-hexopyranosyloxy)-3-(2,6-dideoxy-3-*C*-methyl-3-*O*-methyl-α-L-*ribo*-hexopyranosyloxy)-6,11,12-trihydroxy-9-(2-methoxyethoxy)methoxyimino-2,4,6,8,10,12-hexamethylpentadecan-13-olide [*80214-83-1*]

Roxithromycin contains not less than 970 μg (potency) per mg, calculated on the anhydrous basis. The potency of Roxithromycin is expressed as mass (potency) of roxithromycin ($C_{41}H_{76}N_2O_{15}$).

Description Roxithromycin occurs as a white crystalline powder.

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

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

Optical rotation $[\alpha]_D^{20}$: -93 - $-96°$ (0.5 g calculated on the anhydrous basis, acetone, 50 mL, 100 mm).

Purity **(1)** Heavy metals—Proceed with 2.0 g of Roxithromycin 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).

(2) Related substances—Dissolve 0.040 g of Roxithromycin in the mobile phase A to make 10 mL, and use this solution as the sample solution. Separately, dissolve 0.020 g of Roxithromycin Reference Standard in the mobile phase A to make exactly 10 mL. Pipet 1 mL of this solution, add the mobile phase A to make exactly 100 mL, and use this solution as the standard solution. Perform the test with 20 μL each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions, and determine the peak areas by the automatic integration method: the area of a peak having the relative retention time of about 1.05 to the retention time of roxithromycin from the sample solution is not larger than 2 times of the peak area of roxithromycin from the standard solution. The areas of other than the peak of roxithromycin and the peak having the relative retention time of about 1.05 to the retention time of roxithromycin are not larger than the peak area of roxithromycin from the standard solution, and the total area of the peaks other than roxithromycin from the sample solution is not larger than 6 times of the peak area of roxithromycin from the standard solution.

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 205 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 25 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 25°C.

Mobile phase A: To 200 mL of a solution of ammonium dihydrogenphosphate (17 in 100) add 510 mL of water, and