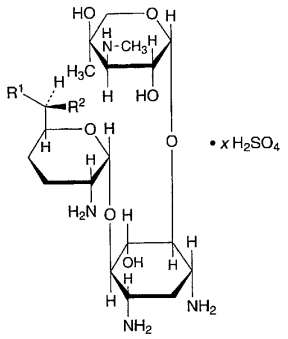
Gentamicin Sulfate

硫酸ゲンタマイシン



Gentamicin sulfate C_1 : R^1=CH_3 R^2=$NHCH_3$
Gentamicin sulfate C_2 : R^1=CH_3 R^2=NH_2
Gentamicin sulfate C_{1a}: R^1=H R_2=NH_2

Gentamicin Sulfate C_1:
O-(6*R*)-2-Amino-2,3,4,6-tetradeoxy-6-methylamino-6-methyl-α-D-*erythro*-hexopyranosyl-(1→4)-*O*-[3-deoxy-4-*C*-methyl-3-methylamino-β-L-arabinopyranosyl-(1→6)]-2-deoxy-D-streptamine sulfate
Gentamicin Sulfate C_2:
O-(6*R*)-2,6-Diamino-2,3,4,6-tetradeoxy-6-methyl-α-D-*erythro*-hexopyranosyl-(1→4)-*O*-[3-deoxy-4-*C*-methyl-3-methylamino-β-L-arabinopyranosyl-(1→6)]-2-deoxy-D-streptamine sulfate
Gentamicin Sulfate C_{1a}:
O-2,6-Diamino-2,3,4,6-tetradeoxy-α-D-*erythro*-hexopyranosyl-(1→4)-*O*-[3-deoxy-4-*C*-methyl-3-methylamino-β-L-arabinopyranosyl-(1→6)]-2-deoxy-D-streptamine sulfate
[*1405-41-0*, Gentamicin Sulfate]

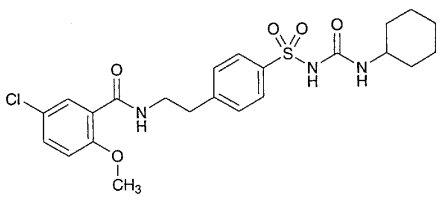
Gentamicin Sulfate conforms to the requirements of Gentamicin Sulfate in the Requirements for Antibiotic Products of Japan.

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

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

Glibenclamide

グリベンクラミド



$C_{23}H_{28}ClN_3O_5S$: 494.00
4-[2-(5-Chloro-2-methoxybenzoylamino)ethyl](*N*-cyclohexylcarbamoyl)benzenesulfonamide [*10238-21-8*]

Glibenclamide, when dried, contains not less than 98.5% of $C_{23}H_{28}ClN_3O_5S$.

Description Glibenclamide occurs as white to pale yellowish white crystals or crystalline powder.

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

Identification **(1)** Determine the absorption spectrum of a solution of Glinbenclamide in methanol (1 in 10,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.

(2) Determine the infrared absorption spectrum of Glibenclamide, previously dried, as directed in the potassium bromide disk 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.

(3) Perform the test with Glibenclamide as directed under the Flame Coloration Test (2): a green color appears.

Melting point 169 - 174°C

Purity **(1)** Heavy metals—Proceed with 1.0 g of Glibenclamide 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).

(2) Related substances—Dissolve 0.20 g of Glibenclamide in 20 mL of chloroform, and use this solution as the sample solution. Pipet 1 mL of the sample solution, and add chloroform to make exactly 20 mL. Pipet 1 mL of this solution, add chloroform to make exactly 10 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10 μL each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of 1-propanol, chloroform and diluted ammonia TS (4 in 5) (11:7:2) to a distance of about 12 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): 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 Not more than 0.5% (1 g, 105°C, 4 hours).

Assay Weigh accurately about 0.9 g of Glibenclamide, previously dried, dissolve in 50 mL of *N,N*-dimethylformamide, and titrate with 0.1 mol/L sodium hydroxide VS (indicator: 3 drops of phenolphthalein TS). Perform a blank determination with a solution prepared by adding 18 mL of water to 50 mL of *N,N*-dimethylformamide, and make any necessary correction.

Each mL of 0.1 mol/L sodium hydroxide VS
= 49.40 mg of $C_{23}H_{28}ClN_3O_5S$

Containers and storage Containers—Tight containers.