

of neostigmine methylsulfate is about 9 minutes.

System suitability—

System performance: Dissolve 0.025 g of Neostigmine Methylsulfate and 4 mg of dimethylaminophenol in 50 mL of the mobile phase. When the procedure is run with 10 μ L of this solution under the above operating conditions, dimethylaminophenol and neostigmine methylsulfate are eluted in this order with the resolution between these peaks being not less than 6.

System repeatability: When the test is repeated 6 times with 10 μ L of the standard solution under the above operating conditions, the relative standard deviation of the peak areas of neostigmine methylsulfate is not more than 1.0%.

Containers and storage Containers—Tight containers.

Neostigmine Methylsulfate Injection

メチル硫酸ネオスチグミン注射液

Neostigmine Methylsulfate Injection is an aqueous solution for injection. It contains not less than 93% and not more than 107% of the labeled amount of neostigmine methylsulfate ($C_{13}H_{22}N_2O_6S$: 334.39).

Method of preparation Prepare as directed under Injections, with Neostigmine Methylsulfate.

Description Neostigmine Methylsulfate Injection is a clear, colorless liquid.

It is slowly affected by light.

pH: 5.0 – 6.5

Identification Take a volume of Neostigmine Methylsulfate Injection equivalent to 5 mg of neostigmine methylsulfate according to the labeled amount, add water to make 10 mL if necessary, and determine the absorption spectrum of this solution as directed under the Ultraviolet-visible Spectrophotometry: it exhibits a maximum between 257 nm and 261 nm.

Bacterial endotoxins Less than 5 EU/mg.

Assay Use Neostigmine Methylsulfate Injection as the sample solution. Separately, weigh accurately about 0.025 g of Neostigmine Methylsulfate Reference Standard, previously dried at 105°C for 3 hours, dissolve in the mobile phase to make exactly 50 mL, and use this solution as the standard solution. Proceed as directed in the Assay under Neostigmine Methylsulfate.

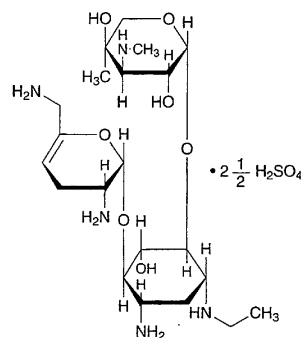
Amount (mg) of neostigmine methylsulfate ($C_{13}H_{22}N_2O_6S$)
= amount (mg) of Neostigmine Methylsulfate

$$\text{Reference Standard} \times \frac{A_T}{A_S}$$

Containers and storage Containers—Hermetic containers.
Storage—Light-resistant.

Netilmicin Sulfate

硫酸ネチルマイシン



$C_{21}H_{41}N_5O_7 \cdot 2\frac{1}{2}H_2SO_4$: 720.78

O-3-Deoxy-4-*C*-methyl-3-methylamino- β -*L*-arabinopyranosyl-(1 \rightarrow 6)-*O*-[2,6-diamino-4,5-dehydro-2,3,4,6-tetra-deoxy- α -*D*-glycero-hexopyranosyl-(1 \rightarrow 4)]-2-deoxy-1-*N*-ethyl-*D*-streptamine hemiheptasulfate [56391-57-2]

Netilmicin Sulfate contains not less than 595 μ g (potency) per mg, calculated on the dried basis. The potency of Netilmicin Sulfate is expressed as mass (potency) of netilmicin ($C_{21}H_{41}N_5O_7$: 475.58).

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

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

It is hygroscopic.

Identification (1) Dissolve 0.03 g of Netilmicin Sulfate in 3 mL of water, and add 0.2 mL of bromine TS: the solution is immediately decolorized.

(2) Dissolve 0.015 g each of Netilmicin Sulfate and Netilmicin Sulfate Reference Standard in 5 mL of water, and use these solutions as the sample solution and the standard solution. Perform the test with these solutions as directed under the Thin-layer chromatography. Spot 5 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 a mixture of methanol, chloroform, ammonia water (28) and acetone (2:2:1:1) to a distance of about 15 cm, and air-dry the plate. Spray evenly 0.2% ninhydrin-water saturated 1-butanol TS on the plate, and heat at 100°C for 5 minutes: the principal spots from the sample solution and the standard solution exhibit a red-purple to red-brown color and show the same R_f value.

(3) A solution of Netilmicin Sulfate (1 in 100) responds to the Qualitative Test (1) for sulfate.

Optical rotation $[\alpha]_D^{20}$: +88 – +96° (0.1 g calculated on the dried basis, water, 10 mL, 100 mm).

pH Dissolve 0.5 g of Netilmicin Sulfate in 5 mL of water: the pH of this solution is between 3.5 and 5.5.

Purity (1) Clarity and color of solution—Dissolve 0.5 g of Netilmicin Sulfate in 5 mL of water: the solution is clear and colorless to light yellow.