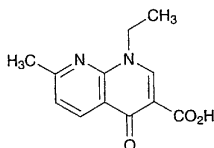


Nalidixic Acid

ナリジクス酸



$C_{12}H_{12}N_2O_3$: 232.24

1-Ethyl-1,4-dihydro-7-methyl-4-oxo-1,8-naphthyridine-3-carboxylic acid [389-08-2]

Nalidixic Acid, when dried, contains not less than 98.5% of $C_{12}H_{12}N_2O_3$.

Description Nalidixic Acid occurs as white to light yellow crystals or crystalline powder. It is odorless.

It is sparingly soluble in chloroform and in *N,N*-dimethylformamide, very slightly soluble in ethanol (95) and in diethyl ether, and practically insoluble in water.

It dissolves in sodium hydroxide TS.

Identification (1) Dissolve 0.10 g of Nalidixic Acid in 0.01 mol/L sodium hydroxide TS to make 100 mL. To 1 mL of the solution add 0.01 mol/L sodium hydroxide TS to make 200 mL. Determine the absorption spectrum of the solution 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) Dissolve 0.02 g of Nalidixic Acid in 2.0 mL of water and 1.0 mL of sulfuric acid, add 0.02 g of vanillin, and boil gently for 2 minutes: the color of the solution changes from yellow to orange-red. Shake this solution vigorously while cooling, and allow to stand for 30 minutes: an orange-yellow precipitate is formed.

Melting point 225 – 231°C

Purity (1) Clarity and color of solution—Dissolve 0.5 g of Nalidixic Acid in 3 mL of sodium hydroxide TS and 7 mL of water: the solution is clear and colorless to pale yellow.

(2) Chloride—To 2.0 g of Nalidixic Acid add 50 mL of water, warm at 70°C for 5 minutes, cool quickly, and filter. To 25 mL of the filtrate add 6 mL of dilute nitric acid and water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution with 0.35 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.012%).

(3) Heavy metals—Proceed with 1.0 g of Nalidixic Acid 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).

(4) Arsenic—Prepare the test solution with 0.40 g of Nalidixic Acid, according to Method 3, and perform the test using Apparatus B (not more than 5 ppm).

(5) Related substances—Dissolve 0.50 g of Nalidixic Acid in 25 mL of chloroform, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add chloroform to make exactly 200 mL, and use this solution as

the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10 μ L 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 ethanol (95), chloroform and ammonia TS (7:2:1) to a distance of about 10 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 0.20% (1 g, 105°C, 3 hours).

Residue on ignition Not more than 0.20% (1 g).

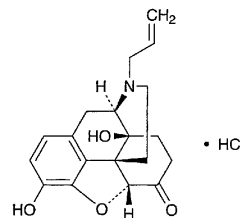
Assay Weigh accurately about 0.3 g of Nalidixic Acid, previously dried, dissolve in 50 mL of *N,N*-dimethylformamide, and titrate with 0.1 mol/L sodium methoxide-dioxane VS, until the color of the solution changes from pale yellow to blue (indicator: 2 drops of thymolphthalein TS). To 50 mL of *N,N*-dimethylformamide add 13 mL of a mixture of 1,4-dioxane and methanol (17:3), perform a blank determination with the solution, and make any necessary correction.

Each mL of 0.1 mol/L sodium methoxide-dioxane VS = 23.224 mg of $C_{12}H_{12}N_2O_3$

Containers and storage Containers—Tight containers.

Naloxone Hydrochloride

塩酸ナロキソン



$C_{19}H_{21}NO_4 \cdot HCl$: 363.84

(5*R*,14*S*)-17-Allyl-4,5-epoxy-3,14-dihydroxymorphinan-6-one monohydrochloride [357-08-4]

Naloxone Hydrochloride contains not less than 98.5% of $C_{19}H_{21}NO_4 \cdot HCl$, calculated on the dried basis.

Description Naloxone Hydrochloride occurs as white to yellowish white, crystals or crystalline powder.

It is freely soluble in water, soluble in methanol, slightly soluble in ethanol (99.5) and in acetic acid (100), and very slightly soluble in acetic anhydride.

It is hygroscopic.

It is gradually colored by light.

Identification (1) Determine the absorption spectrum of a solution of Naloxone Hydrochloride (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