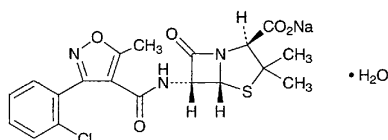


Cloxacillin Sodium

Methylchlorophenylisoxazolylpenicillin Sodium

クロキサシリンナトリウム



$C_{19}H_{17}ClN_3NaO_5S \cdot H_2O$: 475.88

Monosodium (2*S*,5*R*,6*R*)-6-[[3-(2-chlorophenyl)-5-methylisoxazole-4-carbonyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate monohydrate [7081-44-9]

Cloxacillin Sodium contains not less than 824 μ g (potency) per mg, calculated on the anhydrous basis. The potency of Cloxacillin Sodium is expressed as mass (potency) of cloxacillin ($C_{19}H_{18}ClN_3O_5S$: 435.88).

Description Cloxacillin Sodium occurs as white to light yellowish white, crystals or crystalline powder.

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

Identification (1) Determine the absorption spectrum of a solution of Cloxacillin Sodium in chloroform (1 in 20,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of Cloxacillin Sodium Reference Standard: both spectra exhibit similar intensities of absorption at the same wavelength.

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

(3) Cloxacillin Sodium responds to the Qualitative Test (1) for sodium salt.

pH Dissolve 1.0 g of Cloxacillin Sodium in 10 mL of water: the pH of the solution is between 4.5 and 8.0.

Purity Heavy metals—Proceed with 1.0 g of Cloxacillin Sodium 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).

Water Not more than 6.0% (0.2 g, volumetric titration, direct titration).

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.

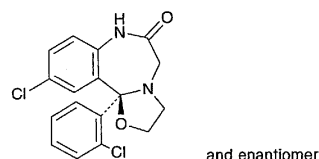
(3) Standard solution—Weigh accurately an amount of Cloxacillin Sodium Reference Standard equivalent to about 0.02 g (potency), and dissolve in 0.05 mol/L phosphate buffer solution, pH 7.0 to make exactly 100 mL. Take exactly a suitable amount of this solution, add 0.05 mol/L phosphate buffer solution, pH 7.0 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 Cloxacillin Sodium equivalent to about 0.02 g (potency), and dissolve in 0.05 mol/L phosphate buffer solution, pH 7.0 to make exactly 100 mL. Take exactly a suitable amount of the solution, add 0.05 mol/L phosphate buffer solution, pH 7.0 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.

Cloxazolam

クロキサゾラム



$C_{17}H_{14}Cl_2N_2O_2$: 349.21

(*RS*)-10-Chloro-11b-(2-chlorophenyl)-2,3,7,11b-tetrahydrooxazolo[3,2-*d*][1,4]benzodiazepin-6(5*H*)-one [24166-13-0]

Cloxazolam, when dried, contains not less than 99.0% of $C_{17}H_{14}Cl_2N_2O_2$.

Description Cloxazolam occurs as white crystals or crystalline powder.

It is odorless and tasteless.

It is freely soluble in acetic acid (100), sparingly soluble in dichloromethane, slightly soluble in ethanol (99.5) and in diethyl ether, very slightly soluble in ethanol (95), and practically insoluble in water.

It dissolves in dilute hydrochloric acid.

It is gradually colored by light.

Melting point: about 200°C (with decomposition).

Identification (1) Dissolve 0.01 g of Cloxazolam in 10 mL of ethanol (99.5) by heating, and add 1 drop of hydrochloric acid: the solution shows a light yellow color and a yellow-green fluorescence under ultraviolet light (main wavelength: 365 nm). Add 1 mL of sodium hydroxide TS to this solution: the color and fluorescence of this solution disappear immediately.

(2) Dissolve 0.01 g of Cloxazolam in 5 mL of dilute hydrochloric acid by heating in a water bath for 10 minutes. After cooling, 1 mL of this solution responds to the Qualitative Tests for primary aromatic amines.