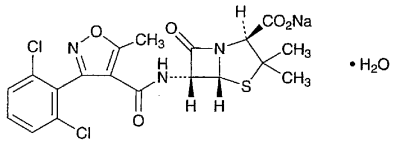
Dicloxacillin Sodium

Methyldichlorophenylisoxazolylpenicillin Sodium

ジクロキサシリンナトリウム



$C_{19}H_{16}Cl_2N_3NaO_5S.H_2O$: 510.32
Monosodium (2*S*,5*R*,6*R*)-6-{[3-(2,6-dichlorophenyl)-5-methylisoxazole-4-carbonyl]amino}-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate monohydrate [*13412-64-1*]

Dicloxacillin Sodium contains not less than 850 μg (potency) per mg, calculated on the anhydrous basis. The potency of Dicloxacillin Sodium is expressed as mass (potency) of dicroxacillin ($C_{19}H_{17}Cl_2N_3O_5S$: 470.33).

Description Dicloxacillin Sodium occurs as a white to light yellowish white crystalline powder.

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

Identification **(1)** Determine the absorption spectrum of a solution of Dicloxacillin Sodium (1 in 2500) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of Dicloxacillin Sodium Reference Standard: both spectra exhibit similar intensities of absorption at the same wavelength.

(2) Determine the infrared absorption spectrum of Dicloxacillin 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 Dicloxacillin Sodium Reference Standard: both spectra exhibit similar intensities of absorption at the same wave numbers.

(3) Dicloxacillin Sodium responds to the Quantitative Test (1) for sodium salt.

Water Not less than 3.0% and not more than 4.5% (0.1 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. Adjust the pH of the medium so that it will be 6.5 to 6.6 after sterilization.

(3) Standard solution—Weigh accurately an amount of Dicloxacillin Sodium Reference Standard equivalent to about 0.05 g (potency), dissolve in phosphate buffer solution, pH 6.0 to make exactly 50 mL, and use this solution as the standard stock solution. Keep the standard stock solution at 5°C or below and use within 24 hours. Take exactly a suitable amount of the standard stock solution before use, add phosphate buffer solution, pH 6.0 to make solutions so that each mL contains 10 μg (potency) and 2.5 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 Dicloxacillin Sodium equivalent to about 0.05 g (potency), dissolve in phosphate buffer solution, pH 6.0 to make exactly 50 mL. Take exactly a suitable amount of the solution, add phosphate buffer solution, pH 6.0 to make solutions so that each mL contains 10 μg (potency) and 2.5 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.

Diethylcarbamazine Citrate

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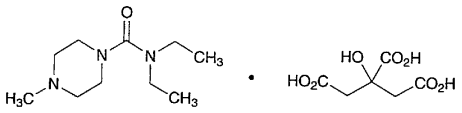

$C_{10}H_{21}N_3O.C_6H_8O_7$: 391.42
N,*N*-Diethyl-4-methylpiperazine-1-carboxamide monocitrate [*1642-54-2*]

Diethylcarbamazine Citrate, when dried, contains not less than 98.0% of $C_{10}H_{21}N_3O.C_6H_8O_7$.

Description Diethylcarbamazine Citrate occurs as a white, crystalline powder. It is odorless, and has an acid and bitter taste.

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

A solution of Diethylcarbamazine Citrate (1 in 20) is acid.

It is hygroscopic.

Identification **(1)** Dissolve 0.5 g of Diethylcarbamazine Citrate in 2 mL of water, add 10 mL of sodium hydroxide TS, and extract with four 5-mL portions of chloroform. Wash the combined chloroform extracts with 10 mL of water, and evaporate the chloroform on a water bath. Add 1 mL of iodoethane to the residue, and boil gently under a reflux condenser for 5 minutes. Evaporate the excess iodoethane with the aid of a current of air, and dissolve the residue in 4 mL of ethanol (95). Cool the ethanol solution in an ice bath, with continuous stirring, add diethyl ether until precipitates are formed, and stir until crystallization is evident. Allow to stand in the ice bath for 30 minutes, and collect the precipitate. Dissolve the precipitate in 4 mL of ethanol (95), repeat the recrystallization in the same manner, then dry at 105°C for 4 hours: the crystals so obtained melt between 151°C and 155°C.

(2) Neutralize the remaining aqueous layer obtained in (1) with dilute sulfuric acid: the solution responds to the Qualitative Tests (2) and (3) for citrate.

Melting point 135.5 – 138.5°C