Bacterial Endotoxins Less than 0.10 EU/mg (potency) of cefuroxime.

Foreign Insoluble Matter Test It meets the requirement.

Insoluble Particulate Matter Test for Injections It meets the requirement.

Uniformity of Dosage Units It meets the requirement.

Assay Weigh accurately about 50 mg (potency) of Cefuroxime Sodium for Injection, according to the labeled potency, dissolve in water to make exactly 50 mL, pipet 5 mL of this solution, add water to make exactly 100 mL, and use this solution as the test solution. Separately, weigh accurately about 50 mg (potency) of Cefuroxime Sodium RS, dissolve in water to make exactly 50 mL, pipet 5 mL of this solution, add water to make exactly 100 mL, and use this solution as the standard solution. Perform the test with 10 μL each of the test solution and standard solution as directed under Liquid Chromatography according to the following conditions, and determine the peak areas, A_T and A_S, of cefuroxime sodium in the test solution and standard solution.

$$\text{Amount [μg (potency)] of cefuroxime } (C_{16}H_{16}N_4O_8S) = \text{Amount [μg (potency)] of Cefuroxime Sodium RS} \times \frac{A_T}{A_S}$$

Operating conditions

Detector: An ultraviolet absorption photometer (wavelength: 254 nm)

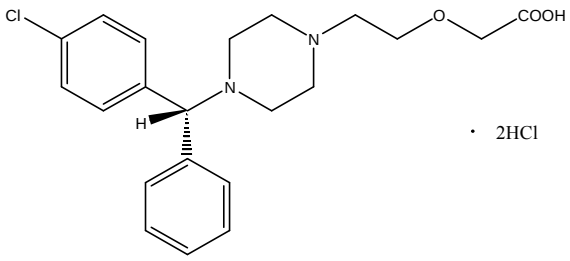
Column: A stainless steel column about 4.6 mm in internal diameter and about 15 cm in length, packed with hexylsilyl silica gel for liquid chromatography (5 μm in particle diameter).

Mobile phase: A mixture of pH 3.4 acetate buffer solution (to 50 mL of 0.1 mol/L sodium acetate add 0.1 mol/L acetic acid to make 1000 mL) and acetonitrile (10 : 1)

Flow rate: 2.0 mL/minute

Containers and Storage ***Containers***—Hermetic containers.

Cetirizine Dihydrochloride



and enantiomer

$C_{21}H_{25}ClN_2O_3 \cdot 2HCl$: 461.81

2-[2-{4-[(4-Chlorophenyl)phenylmethyl]piperazin-1-yl}ethoxy]acetic acid dihydrochloride [*83881-52-1*]

Cetirizine Dihydrochloride contains not less than 99.0 % and not more than 100.5 % of cetirizine dihydrochloride ($C_{21}H_{25}ClN_2O_3 \cdot 2HCl$), calculated on an anhydrous basis.

Description Cetirizine Dihydrochloride is a white powder.

Cetirizine Dihydrochloride is freely soluble in water, and practically insoluble in acetone or in methylene chloride.

Identification (1) Dissolve 20.0 mg of Cetirizine Dihydrochloride in 0.1 mol/L hydrochloric acid to make 100 mL. Dilute 10.0 mL of this solution with 0.1 mol/L hydrochloric acid to 100 mL. Determine the absorption spectrum of this solution as directed under Ultraviolet-visible Spectrophotometry. Absorption maximum occurs at 231 nm, and the specific absorbance at this wavelength ranges from 359 to 381.

(2) Determine the infrared spectra of Cetirizine Dihydrochloride and Cetirizine Dihydrochloride RS as directed in the potassium bromide disk method under Infrared Spectrophotometry: both spectra exhibit similar intensities of absorption at the same wavenumbers.

(3) Dissolve 10 mg of Cetirizine Dihydrochloride in water to make 5 mL, and use this solution as the test solution. Separately, dissolve 10 mg of Cetirizine Dihydrochloride RS in water to make 5 mL, and use this solution as the standard solution (1). Separately, dissolve 10 mg of chlorphenamine maleate RS in water to make 5 mL. To 1 mL of the solution, add 1 mL of the standard solution (1). Use this solution as the standard solution (2). Perform the test with these solutions as directed under Thin-layer Chromatography. Spot 5 μL each of the test solution and the standard solutions (1) and (2) on a plate of silica gel with fluorescent indicator for thin-layer chromatography, develop with a mixture of methylene chloride, methanol, and ammonia solution (28) (90 : 10 : 1) to a distance of about 15 cm, and dry the plate in cool air. Examine in ultraviolet light at 254 nm, and compare the principal spot from the test solution with that from the standard