this solution, using tetramethylsilane for nuclear magnetic resonance spectroscopy as an internal reference compound, as directed under the Nuclear Magnetic Resonance Spectroscopy (^{1}H): it exhibits a single signal A at around δ 4.7 ppm, and a multiple signal B between δ 6.5 ppm and δ 7.4 ppm. The ratio of integrated intensity of these signals, A:B, is about 1:1.

Optical rotation $[\alpha]_D^{20}$: -75 – $-88°$ (0.45 g calculated on the anhydrous bases, a solution of sodium hydrogen carbonate (1 in 50), 50 mL, 100 mm).

Purity Dissolve 0.1 g of Cefixime in 100 mL of 0.1 mol/L phosphate buffer solution, pH 7.0, and use this solution as the sample solution. Perform the test with 10 μL of the sample solution as directed under the Liquid Chromatography according to the following conditions, measure the areas of the peaks by the automatic integration method, and calculate the amounts of these peak areas by the area percentage method: the amount of each peak area other than cefixime is not more than 1.0%, and the total area of the peaks other than cefixime is not more than 2.5%.

Operating conditions—

Detector, column, column temperature, mobile phase, and flow rate: Proceed as directed in the operating conditions in the Assay.

Time span of measurement: About 3 times as long as the retention time of cefixime after the solvent peak.

System suitability—

Test for required detection: Pipet 1 mL of the sample solution, and add 0.1 mol/L phosphate buffer solution, pH 7.0 to make exactly 100 mL. Confirm that the peak height of cefixime obtained from 10 μL of this solution is equivalent to 20 to 60 mm.

System performance: Dissolve about 2 mg of Cefixime Reference Standard in 200 mL of 0.1 mol/L phosphate buffer solution, pH 7.0, and use this solution as the solution for system suitability test. When the procedure is run with 10 μL of the solution according to the above operating conditions, the number of theoretical steps and the symmetry coefficient of the peak of cefixime are not less than 4000 and not more than 2.0, respectively.

System repeatability: When the test is repeated 6 times with 10 μL of the solution for system suitability test under the above operating conditions, the relative standard deviation of the peak areas of cefixime is not more than 2.0%.

Water Not less than 9.0 and not more than 12.0% (0.1 g, volumetric titration, direct titration).

Residue on ignition Not more than 0.10% (1.0 g).

Assay Weigh accurately an amount of Cefixime and Cefixime Reference Standard, equivalent to about 0.1 g (potency), and dissolve in 0.1 mol/L phosphate buffer solution, pH 7.0 to make exactly 100 mL each. Pipet 10 mL each of these solutions, add 0.1 mol/L phosphate buffer solution, pH 7.0 to make exactly 50 mL each, and use these solutions as the sample solution and the standard solution, respectively. Perform the test with exactly 10 μL each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions, and calculate the peak areas, A_T and A_S, of cefixime of these solutions.

Amount [μg (potency)] of cefixime ($C_{16}H_{15}N_5O_7S_2$)

= amount [mg (potency)] of Cefixime Reference Standard $\times \frac{A_T}{A_S} \times 1000$

Operating conditions—

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

Column: A stainless steel column 4.6 mm in inside diameter and 125 mm in length, packed with octadecylsilanized silica gel for liquid chromatography (4 μm in particle diameter).

Column temperature: A constant temperature of about 40°C.

Mobile phase: To 25 mL of a solution of tetrabutylammonium hydroxide TS (10 in 13) add water to make 1000 mL, adjust to pH 6.5 with diluted phosphoric acid (1 in 10). To 300 mL of this solution add 100 mL of acetonitrile.

Flow rate: Adjust the flow rate so that the retention time of cefixime is about 10 minutes.

System suitability—

System performance: When the procedure is run with 10 μL of the standard solution under the above operating conditions, the number of theoretical steps and the symmetry coefficient of the peak of cefixime are not less than 4000 and not more than 2.0, respectively.

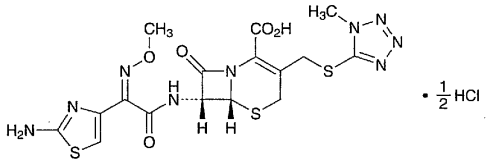
System repeatability: When the test is repeated 6 times with 10 μL of the standard solution under the above operating conditions, the relative standard deviation of peak areas of cefixime is not more than 2.0%.

Containers and storage Containers—Tight containers.

Storage—Light-resistant.

Cefmenoxime Hydrochloride

塩酸セフメノキシム



$C_{16}H_{17}N_9O_5S_3.\frac{1}{2}HCl$: 529.79

(6*R*,7*R*)-7-[(*Z*)-2-(2-Aminothiazol-4-yl)-2-methoxyiminoacetylamino]-3-(1-methyl-1*H*-tetrazol-5-ylsulfanylmethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid hemihydrochloride [*75738-58-8*]

Cefmenoxime Hydrochloride conforms to the requirements of Cefmenoxime Hydrochloride in the Requirements for Antibiotic Products of Japan.

Description Cefmenoxime Hydrochloride occurs as white to light orange-yellow crystals or crystalline powder.

It is freely soluble in formamide, slightly soluble in methanol, very slightly soluble in water, and practically insoluble in ethanol (95) and in diethyl ether.