Internal standard solution—A solution of dimedon in 0.05 mol/L phosphate buffer solution, pH 7.0 (11 in 10,000).

Operating conditions—

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

Column: A stainless steel column 4.6 mm in inside diameter and 10 cm in length, packed with hexasilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 25°C.

Mobile phase: Dissolve 4.26 g of anhydrous disodium hydrogenphosphate and 2.72 g of potassium dihydrogenphosphate in 980 mL of water, and add 20 mL of acetonitrile.

Flow rate: Adjust the flow rate so that the retention time of ceftazidime is about 4 minutes.

System suitability—

System performance: When the procedure is run with 5 μL of the standard solution under the above operating conditions, the internal standard and ceftazidime are eluted in this order with the resolution between these peaks being not less than 3.

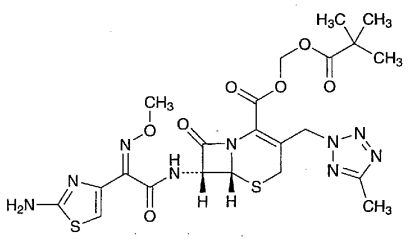
System repeatability: When the test is repeated 6 times with 5 μL of the standard solution under the above operating conditions, the relative standard deviation of the ratios of the peak area of ceftazidime to that of the internal standard is not more than 1.0%.

Containers and storage Containers—Tight containers.

Storage—Light-resistant.

Cefteram Pivoxil

セフテラムピボキシル



$C_{22}H_{27}N_9O_7S_2$: 593.64

2,2-Dimethylpropanoyloxymethyl (6*R*,7*R*)-7-[(*Z*)-2-(2-aminothiazol-4-yl)-2-methoxyiminoacetylamino]-3-(5-methyl-2*H*-tetrazol-2-ylmethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate [*82547-58-8*, Cefteram]

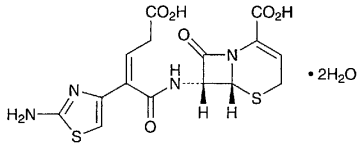
Cefteram Pivoxil conforms to the requirements of Cefteram Pivoxil in the Requirements for Antibiotic Products of Japan.

Description Cefteram Pivoxil occurs as a white to yellowish white powder. It has a bitter taste.

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

Ceftibuten

セフチブテン



$C_{15}H_{14}N_4O_6S_2.2H_2O$: 446.46

(6*R*,7*R*)-7-[(*Z*)-2-(2-Aminothiazol-4-yl)-4-carboxybut-2-enoylamino]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid dihydrate [*118081-34-8*]

Ceftibuten contains not less than 900 μg (potency) per mg, calculated on the anhydrous basis. The potency of Ceftibuten is expressed as mass (potency) of ceftibuten ($C_{15}H_{14}N_4O_6S_2$: 410.42).

Description Ceftibuten occurs as a white to pale yellowish white crystalline powder and has a slight, characteristic odor.

It is freely soluble in *N,N*-dimethylformamide and in dimethyl sulfoxide, and practically insoluble in water, in ethanol (95) and in diethyl ether.

Identification (1) Determine the absorption spectrum of a solution of Ceftibuten in 0.1 mol/L phosphate buffer solution for ceftibuten, pH 8.0 (1 in 50,000) as directed under the Ultraviolet-visible Spectrophotometry: it exhibits a maximum between 261 nm and 265 nm.

(2) Determine the infrared absorption spectrum of Ceftibuten as directed in the paste method under the Infrared Spectrophotometry: it exhibits absorption at the wave numbers of about 3249 cm^{-1}, 1772 cm^{-1}, 1700 cm^{-1}, 1651 cm^{-1} and 1544 cm^{-1}.

(3) Determine the spectrum of a solution of Ceftibuten in deuterated dimethyl sulfoxide for nuclear magnetic resonance spectroscopy (1 in 30), using tetramethylsilane for nuclear magnetic resonance spectroscopy as an internal reference compound, as directed under the Nuclear Magnetic Resonance Spectroscopy (^1H): it exhibits double signals A and B, at around δ 3.2 ppm and at around δ 5.1 ppm, a quartet signal C, at around δ 5.8 ppm, and a single signal D, at around δ 6.3 ppm. The ratio of integrated intensity of each signal except the signal at around δ 3.2 ppm, B:C:D is about 1:1:1.

Absorbance $E^{1\%}_{1\,cm}$ (263 nm): 320 – 345 (0.02 g calculated on the anhydrous basis, 0.1 mol/L phosphate buffer solution for ceftibuten, pH 8.0, 1000 mL).

Optical rotation $[\alpha]^{20}_D$: +135 – +155° (0.3 g calculated on the anhydrous basis, 0.1 mol/L phosphate buffer solution for ceftibuten, pH 8.0, 50 mL, 100 mm).

Purity (1) Heavy metals—Proceed with 2.0 g of Ceftibuten according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(2) Related substances—Being specified separately.

Water Not less than 8.0% and not more than 13.0% (0.2 g, volumetric titration, direct titration. Use a mixture of