

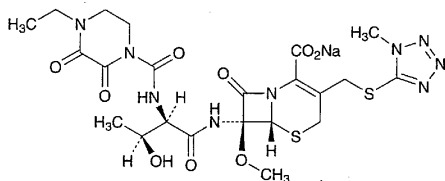
than 4.

System repeatability: When the test is repeated 5 times with 5 μ L of the standard solution under the above operating conditions, the relative standard deviation of the peak area of cefazolin is not more than 1.0%.

Containers and storage Containers—Hermetic containers.
Storage—Light-resistant.

Cefbuperazone Sodium

セフブペラゾンナトリウム



$C_{22}H_{28}N_9NaO_9S_2$: 649.63

Monosodium (6*R*,7*S*)-7-[(2*R*,3*S*)-2-[(4-ethyl-2,3-dioxopiperazine-1-carbonyl)amino]-3-hydroxybutanoylamino]-7-methoxy-3-(1-methyl-1*H*-tetrazol-5-ylsulfanylmethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate [76648-01-6]

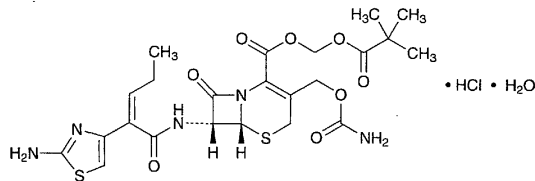
Cefbuperazone Sodium conforms to the requirements of Cefbuperazone Sodium in the Requirements for Antibiotic Products of Japan.

Description Cefbuperazone Sodium occurs as a white to light yellowish white powder.

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

Cefcapene Pivoxil Hydrochloride

塩酸セフカペン ピボキシル



$C_{23}H_{29}N_5O_8S_2 \cdot HCl \cdot H_2O$: 622.11

2,2-Dimethylpropanoyloxymethyl (6*R*,7*R*)-7-[(*Z*)-2-(2-aminothiazol-4-yl)pent-2-enylamino]-3-carbamoyloxymethyl-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate monohydrochloride monohydrate [147816-24-8]

Cefcapene Pivoxil Hydrochloride contains not less than 722 μ g (potency) per mg, calculated on the anhydrous basis. The potency of Cefcapene Pivoxil

Hydrochloride is expressed as mass (potency) of cefcapene ($C_{17}H_{19}N_5O_6S_2$: 453.49).

Description Cefcapene Pivoxil Hydrochloride occurs as a white to pale yellowish white, crystalline powder or mass. It has slightly a characteristic odor.

It is freely soluble in *N,N*-dimethylformamide and in methanol, sparingly soluble in ethanol (95), and slightly soluble in water.

Identification (1) Determine the infrared absorption spectra of Cefcapene Pivoxil Hydrochloride and Cefcapene Pivoxil Hydrochloride Reference Standard as directed in the paste method under the Infrared Spectrophotometry, and compare these spectra: both spectra exhibit similar intensities of absorption at the same wave numbers.

(2) Determine the spectrum of a solution of Cefcapene Pivoxil Hydrochloride in deuterated methanol for nuclear magnetic resonance spectroscopy (1 in 50) as directed under the Nuclear Magnetic Resonance Spectroscopy (1H), using tetramethylsilane for nuclear magnetic resonance spectroscopy as an internal reference compound: it exhibits a triplet signal A at around δ 6.3 ppm, and a single signal B at around δ 6.7 ppm, and the ratio of integrated intensity of each signal, A:B, is about 1:1.

(3) Dissolve 0.01 g of Cefcapene Pivoxil Hydrochloride in 2 mL of a mixture of water and methanol (1:1), and add 1 drop of silver nitrate TS: a white precipitate is formed.

Absorbance $E_{1\text{cm}}^{1\%}$ (265 nm): 255 – 285 (0.03 g calculated on the anhydrous basis, a mixture of acetate buffer solution, pH 5.5 and methanol (1:1), 2000 mL).

Optical rotation $[\alpha]_D^{20}$: +51 – +54° (0.1 g calculated on the anhydrous basis, methanol, 10 mL, 100 mm).

Purity (1) Heavy metals—Proceed with 2.0 g of Cefcapene Pivoxil Hydrochloride according to Method 4, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(2) Related substance I—Dissolve an amount of Cefcapene Pivoxil Hydrochloride, equivalent to about 0.01 g (potency), in 2 mL of methanol, add a mixture of water and methanol (1:1) to make 50 mL, and use this solution as the sample solution. Perform the test with 30 μ L of the sample solution as directed under the Liquid Chromatography according to the following conditions. If necessary, correct the change of the base-line by performing in the same manner as the test with 30 μ L of a mixture of water and methanol (1:1). Determine each peak area by the automatic integration method: the total area of the peaks other than cefcapene pivoxil and other than the solvent is not more than 1.5% of the total area of the peaks other than the solvent.

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 265 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μ m in particle diameter).

Column temperature: A constant temperature of about 20°C.

Mobile phase A: Dissolve 5.99 g of potassium dihydrogenphosphate in water to make 1100 mL. To this solution add a solution prepared by dissolving 1.89 g of tetra-*n*-pentylam-