this order with the resolution between these peaks being not less than 5.

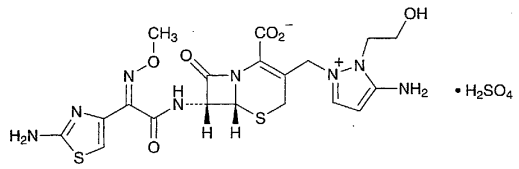
System repeatability: When the test is repeated 6 times with 10 μL of the standard solution under the above operating conditions, the relative standard deviation of the ratios of the peak area of cefoperazone to that of the internal standard is not more than 1.0%.

Containers and storage Containers—Hermetic containers.

Storage—In a cold place.

Cefoselis Sulfate

硫酸セフォセリス



$C_{19}H_{22}N_8O_6S_2.H_2SO_4$: 620.64

(6*R*,7*R*)-3-{[3-Amino-2-(2-hydroxyethyl)-2*H*-pyrazol-1-ium-1-yl]methyl}-7-[(*Z*)-2-(2-aminothiazol-4-yl)-2-methoxyiminoacetylamino]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate monosulfate

[*122841-12-7*]

Cefoselis Sulfate contains not less than 770 μg (potency) per mg, calculated on the anhydrous basis. The potency of Cefoselis Sulfate is expressed as mass (potency) of cefoselis ($C_{19}H_{22}N_8O_6S_2$: 522.56).

Description Cefoselis Sulfate occurs as a white to pale yellowish white crystalline powder.

It is freely soluble in dimethyl sulfoxide, sparingly soluble in water, and practically insoluble in ethanol (95) and in diethyl ether.

It is hygroscopic.

Identification **(1)** Determine the absorption spectra of solutions of Cefoselis Sulfate and Cefoselis Sulfate Reference Standard (1 in 80,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectra: both spectra exhibit similar intensities of absorption at the same wavelengths.

(2) Determine the infrared absorption spectra of Cefoselis Sulfate and Cefoselis Sulfate Reference Standard as directed in the paste method under the Infrared Spectrophotometry, and compare the spectra: both spectra exhibit similar intensities of absorption at the same wave numbers.

(3) Determine the spectrum of a solution of Cefoselis Sulfate in deuterated dimethyl sulfoxide for nuclear magnetic resonance spectroscopy (1 in 20), using tetramethylsilane for nuclear magnetic sesonance spectroscopy as an internal reference compound, as directed under the Nuclear Magnetic Resonance Spectroscopy (^1H): it exhibits a triple signal A at around δ 3.6 ppm, single signals B and C, at around δ 3.8 ppm and at around δ 6.7 ppm, and a double signal D, at around δ 8.0 ppm. The ratio of integrated intensity of each signal, A:B:C:D, is about 2:3:1:1.

(4) A solution of Cefoselis Sulfate (1 in 100) responds to the Qualitative Test (1) for sulfate salt.

Optical rotation $[\alpha]_D^{25}$: −26 – −31° (0.4 g, dimethyl sulfoxide, 20 mL, 100 mm).

pH Dissolve 0.1 g of Cefoselis Sulfate in 10 mL of water: the pH of the solution is between 1.8 and 2.4.

Purity **(1)** Heavy metals—Proceed with 2.0 g of Cefoselis Sulfate according to Method 4, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution. Use a solution of magnesium nitrate hexahydrate in ethanol (95) (3 in 10) instead of a solution of magnesium nitrate hexahydrate in ethanol (95) (1 in 10) (not more than 10 ppm).

(2) Arsenic—Being specified separately.

(3) Related substances—Being specified separately.

(4) Monoethanolamine—Being specified separately.

(5) Residual solvents—Being specified separately.

Water Not more than 1.0% (0.5 g, volumetric titration, direct titration. Use a mixture of formamide for water determination and methanol for water determination (2:1) instead of methanol for water determination. Taking care the sampling to avoid moisture absorption).

Residue on ignition Being specified separately.

Foreign Insoluble Matter Test Being specified separately.

Bacterial endotoxins Less than 0.05 EU/mg (potency). Use tris buffer solution for bacterial endotoxins test instead of water for bacterial endotoxins test as the diluent of the standard solution and as the solution for endotoxin spike of gel-clot technique or turbidimetric technique.

Sterility Being specified separately.

Assay Weigh accurately an amount of Cefoselis Sulfate and Cefoselis Sulfate Reference Standard, equivalent to about 0.025 g (potency), dissolve in 0.1 mol/L phosphate buffer solution, pH 7.0 to make exactly 100 mL, and use these solutions as the sample solution and the standard solution. Perform the test with 5 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 cefoselis of each solution.

$$\text{Amount [}\mu\text{g (potency)] of cefoselis } (C_{19}H_{22}N_8O_6S_2) = \text{amount [mg (potency)] of Cefoselis Sulfate Reference Standard} \times \frac{A_T}{A_S} \times 1000$$

Operating conditions—

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

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

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

Mobile phase: A mixture of phosphate buffer solution, pH 6.5 and acetonitrile for liquid chromatography (10:1).

Flow rate: Adjust the flow rate so that the retention time of cefoselis is about 5 minutes.

System suitability—

System performance: Dissolve 2.5 mg each of Cefoselis Sulfate Reference Standard and cefoselis-3-ene-isomer in 10 mL of 0.1 mol/L phosphate buffer solution, pH 7.0. When the procedure is run with 5 μL of this solution under the above operating conditions, cefoselis-3-ene-isomer and cefoselis are eluted in this order with the resolution between these peaks being not less than 2.9.

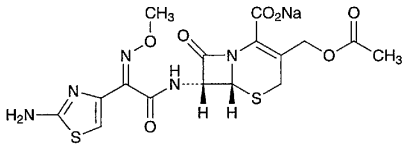
System repeatability: When the test is repeated 6 times with 5 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak areas of cefoselis is not more than 1.0%.

Containers and storage Containers—Hermetic containers.

Storage—Light-resistant, and in a cold place.

Cefotaxime Sodium

セフォタキシムナトリウム



$C_{16}H_{16}N_5NaO_7S_2$: 477.45

Monosodium (6*R*,7*R*)-3-acetoxymethyl-7-[(*Z*)-2-(2-aminothiazol-4-yl)-2-methoxyiminoacetylamino]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate [*64485-93-4*]

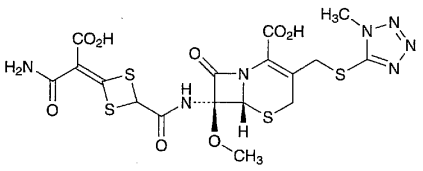
Cefotaxime Sodium conforms to the requirements of Cefotaxime Sodium in the Requirements for Antibiotic Products of Japan.

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

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

Cefotetan

セフォテタン



$C_{17}H_{17}N_7O_8S_4$: 575.62

(6*R*,7*R*)-7-{[4-(Carbamoylcarboxymethylene)-1,3-dithietane-2-carbonyl]amino}-7-methoxy-3-(1-methyl-1*H*-tetrazol-5-ylsulfanylmethyl)-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid [*69712-56-7*]

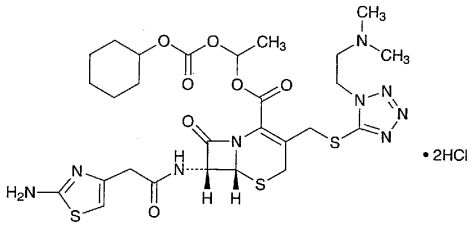
Cefotetan conforms to the requirements of Cefotetan in the Requirements for Antibiotic Products of Japan.

Description Cefotetan occurs as a white to light yellowish white crystalline powder.

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

Cefotiam Hexetil Hydrochloride

塩酸セフォチアムヘキセチル



$C_{27}H_{37}N_9O_7S_3.2HCl$: 768.76

(*RS*)-1-Cyclohexyloxycarbonyloxyethyl (6*R*,7*R*)-7-[2-(2-aminothiazol-4-yl)acetylamino]-3-[1-(2-dimethylaminoethyl)-1*H*-tetrazol-5-ylsulfanylmethyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate dihydrochloride [*95789-30-3*]

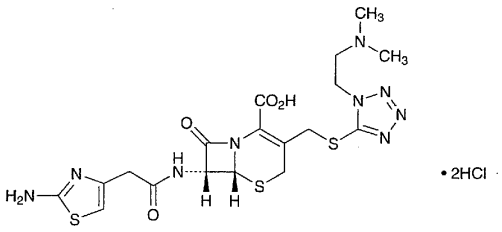
Cefotiam Hexetil Hydrochloride conforms to the requirements of Cefotiam Hexetil Hydrochloride in the Requirements for Antibiotic Products of Japan.

Description Cefotiam Hexetil Hydrochloride occurs as a white to light yellow powder. It has a faint characteristic odor and a bitter taste.

It is very soluble in water, in 0.1 mol/L hydrochloric acid TS, in methanol and in ethanol (95), freely soluble in dimethylsulfoxide, and practically insoluble in diethyl ether.

Cefotiam Hydrochloride

塩酸セフォチアム



$C_{18}H_{23}N_9O_4S_3.2HCl$: 598.55

(6*R*,7*R*)-7-[2-(2-Aminothiazol-4-yl)acetylamino]-3-[1-(2-dimethylaminoethyl)-1*H*-tetrazol-5-ylsulfanylmethyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid dihydrochloride [*66309-69-1*]