dine, dissolve in the mobile phase to make exactly 50 mL, and use this solution as the sample solution. Separately, take exactly 0.025 g of Cefalexin Reference Standard, dissolve in the mobile phase to make exactly 250 mL, and use this solution as the standard solution. Perform the test with 5 μL each of these solutions as directed under the Liquid Chromatography according to the following conditions, and calculate the areas of each peak by the automatic integration method: the peak area of cefalexin from the sample solution is not more than the peak area of cefalexin from the standard solution.

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: Dissolve 6.8 g of potassium dihydrogenphosphate in 800 mL of water, adjust the pH to 3.0 with diluted phosphoric acid (1 in 10), and add water to make 1000 mL. To 700 mL of this solution add 100 mL of acetonitrile.

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

System suitability—

System performance: When the procdure is run with 5 μL of the sample solution under the above operating conditions, cefalexin and cefradine are eluted in this order with the resolution between these peaks being not less than 4.

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 cefalexin is not more than 2.0%.

Water Not more than 6.0% (0.2 g, volumetric titration, direct titration).

Assay Perform the test according to the Cylinder-plate method as directed under the Microbial Assay for Antibiotics according to the following conditions.

(1) Test organism—*Bacillus subtilis* ATCC 6633

(2) Culture medium—Use the medium i in 1) Medium for test organism [5] under (1) Agar media for seed and base layer. Adjust the pH of the medium so that it will be 6.2 to 6.4 after sterilization.

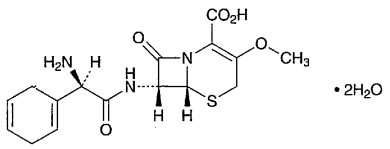
(3) Standard solution—Weigh accurately an amount of Cefradine Reference Standard equivalent to about 0.02 g (potency), dissolve in phosphate buffer solution, pH 6.0 to make exactly 50 mL. Take exactly a suitable amount of this solution, add phosphate buffer solution, pH 6.0 to make solutions so that each mL contains 20 μg (potency) and 5 μg (potency), and use these solutions as the high concentration standard solution and the low concentration standard solution, respectively.

(4) Sample solution—Weigh accurately an amount of Cefradine equivalent to about 0.02 g (potency), dissolve in phosphate buffer solution, pH 6.0 to make exactly 50 mL. Take exactly a suitable amount of this solution, add phosphate buffer solution, pH 6.0 to make solutions so that each mL contains 20 μg (potency) and 5 μg (potency), and use these solutions as the high concentration sample solution and the low concentration sample solution, respectively.

Containers and storage Containers—Tight containers.

Cefroxadine

セフロキサジン



$C_{16}H_{19}N_3O_5S.2H_2O$: 401.43

(6*R*,7*R*)-7-[(2*R*)-2-Amino-2-cyclohexa-1,4-dienylacetylamino]-3-methoxy-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid dihydrate [*51762-05-1*, anhydride]

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

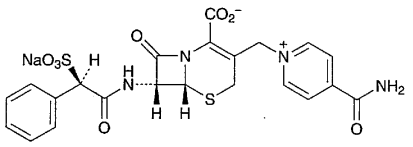
Description Cefroxadine occurs as pale yellowish white to light yellow crumbly, crystalline grains or powder. It has a characteristic odor.

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

It dissolves in 0.1 mol/L hydrochloric acid TS.

Cefsulodin Sodium

セフスロジンナトリウム



$C_{22}H_{19}N_4NaO_8S_2$: 554.53

Monosodium (6*R*,7*R*)-3-(4-carbamoylpyridinium-1-ylmethyl)-8-oxo-7-[(2*R*)-2-phenyl-2-sulfonatoacetylamino]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate [*52152-93-9*]

Cefsulodin Sodium contains not less than 864 μg (potency) per mg, calculated on the anhydrous basis. The potency of Cefsulodin Sodium is expressed as mass (potency) of cefsulodin ($C_{22}H_{20}N_4O_8S_2$: 532.55).

Description Cefsulodin Sodium occurs as white to light yellow, crystals or crystalline powder.

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

It is hygroscopic.

Identification **(1)** Determine the absorption spectrum of a solution of Cefsulodin Sodium (1 in 50,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum