spectra exhibit similar intensities of absorption at the same wave numbers.

(4) A solution of Carteolol Hydrochloride (1 in 50) responds to the Qualitative Tests for chloride.

Purity **(1)** Clarity and color of solution—Dissolve 1.0 g of Carteolol Hydrochloride in 30 mL of water: the solution is clear and colorless.

(2) Heavy metals—Proceed with 2.0 g of Carteolol Hydrochloride 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).

(3) Arsenic—Prepare the test solution with 1.0 g of Carteolol Hydrochloride according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).

(4) Related substances—Dissolve 0.20 g of Carteolol Hydrochloride in 10 mL of methanol, and use this solution as the sample solution. Pipet 2 mL of the sample solution, and add methanol to make exactly 100 mL. Pipet 1 mL of this solution, add methanol to make exactly 10 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10 μL each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of chloroform, methanol and ammonia solution (28) (50:20:1) to a distance of about 12 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Loss on drying Not more than 0.5% (1 g, 105°C, 3 hours).

Residue on ignition Not more than 0.10% (1 g).

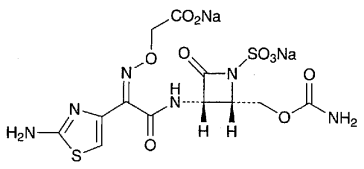
Assay Weigh accurately about 0.5 g of Carteolol Hydrochloride, previously dried, add 30 mL of acetic acid (100), dissolve by heating on a water bath, and cool. After adding 70 mL of acetic anhydride, titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 32.884 mg of $C_{16}H_{24}N_2O_3.HCl$

Containers and storage Containers—Well-closed containers.

Carumonam Sodium

カルモナムナトリウム



$C_{12}H_{12}N_6Na_2O_{10}S_2$: 510.37
Disodium (*Z*)-{(2-aminothiazol-4-yl)[(2*S*,3*S*)-2-carbamoyloxymethyl-4-oxo-1-sulfonatoazetidin-3-ylcarbamoyl]methyleneaminooxy}acetate [*86832-68-0*]

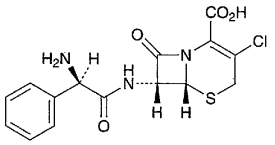
Carumonam Sodium conforms to the requirements of Carumonam Sodium in the Requirements for Antibiotic Products of Japan.

Description Carumonam Sodium occurs as white to pale orange yellowish white crystals or crystalline powder.

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

Cefaclor

セファクロル



$C_{15}H_{14}ClN_3O_4S$: 367.81
(6*R*,7*R*)-7-[(2*R*)-2-Amino-2-phenylacetylamino]-3-chloro-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid [*53994-73-3*]

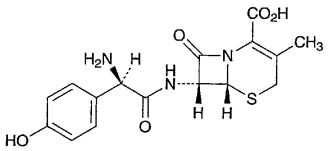
Cefaclor conforms to the requirements of Cefaclor in the Requirements for Antibiotic Products of Japan.

Description Cefaclor occurs as a white to yellowish white crystalline powder.

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

Cefadroxil

セファドロキシル



$C_{16}H_{17}N_3O_5S$: 363.39
(6*R*,7*R*)-7-[(2*R*)-2-Amino-2-(4-hydroxyphenyl)acetylamino]-3-methyl-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid [*50370-12-2*]

Cefadroxil contains not less than 950 μg (potency) per mg, calculated on the anhydrous basis. The potency of Cefadroxil is expressed as mass (potency) of cefadroxil ($C_{16}H_{17}N_3O_5S$: 363.39).

Description Cefadroxil occurs as a white to light yellow-white powder.

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

Identification (1) Determine the absorption spectrum of a solution of Cefadroxil (1 in 50,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of Cefadroxil Reference Standard: both spectra exhibit similar intensities of absorption at the same wavelength.

(2) Determine the infrared absorption spectrum of Cefadroxil as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of Cefadroxil Reference Standard: both spectra exhibit similar intensities of absorption at the same wave numbers.

(3) Determine the spectrum of a solution of Cefadroxil in a mixture of heavy water for nuclear magnetic resonance spectroscopy and deuterated hydrochloric acid (3:1) (1 in 10), using sodium 3-(trimethylsilyl)propionate-d_4 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 2.1 ppm, a double signal B at around δ 7.0 ppm, and a double signal C at around δ 7.5 ppm. The ratio of integrated intensity of each signal, A:B:C, is about 3:2:2.

Absorbance $E^{1\%}_{1cm}$ (262 nm): 220 – 240 (0.1 g calculated on the anhydrous basis, water, 5000 mL).

Optical rotation $[\alpha]^{25}_D$: +164 – +182° (0.6 g calculated on the anhydrous basis, water, 100 mL, 100 mm).

pH Dissolve 1.0 g of Cefadroxil in 200 mL of water: pH of the solution is between 4.0 and 6.0.

Purity (1) Heavy metals—Proceed with 1.0 g of Cefadroxil according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(2) Related substances—Dissolve 0.1 g of Cefadroxil in 4 mL of a mixture of ethanol (99.5), water and diluted hydrochloric acid (1 in 5) (75:22:3), and use this solution as the sample solution. Pipet 1 mL of the sample solution, add a mixture of ethanol (99.5), water and diluted hydrochloric acid (1 in 5) (75:22:3) to make exactly 100 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 2 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop with a mixture of ethyl acetate, water, ethanol (99.5) and formic acid (14:5:5:1) to a distance of about 12 cm, and air-dry the plate. Spray evenly ninhydrin-citric acid-acetic acid TS on the plate, and heat at 100°C for 10 minutes: the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Water Not less than 4.2% and not more than 6.0% (0.5 g, volumetric titration, direct titration).

Assay Weigh accurately an amount of Cefadroxil and Cefadroxil Reference Standard equivalent to about 0.05 g (potency), dissolve each in water to make exactly 500 mL, and use these solutions as the sample solution and the standard solution, respectively. Perform the test with 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 cefadroxil of the solutions.

Amount [μg (potency)] of $C_{16}H_{17}N_3O_5S$
= amount [mg (potency)] of Cefadroxil Reference Standard $\times \frac{A_T}{A_S} \times 1000$

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 262 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 25 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

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

Mobile phase: A mixture of a solution of potassium dihydrogenphosphate (17 in 12,500) and methanol (17:3).

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

System suitability—

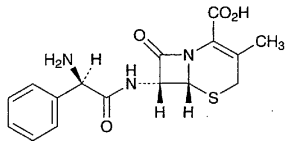
System performance: Dissolve about 5 mg (potency) of Cefadroxil and about 0.01 g (potency) of Propylene Glycol Cefatrizine in 50 mL of water. When the procedure is run with 10 μL of this solution under the above operating conditions, cefadroxil and cefatrizine are eluted in this order with the resolution between these peaks being not less than 4.

System repeatability: When the test is repeated 6 times with 10 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak areas of cefadroxil is not more than 1.0%.

Containers and storage Containers—Tight containers.

Cefalexin

セファレキシン



$C_{16}H_{17}N_3O_4S$: 347.39

(6*R*,7*R*)-7-[(2*R*)-2-Amino-2-phenylacetylamino]-3-methyl-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid [*15686-71-2*]

Cefalexin contains not less than 950 μg (potency) and not more than 1030 μg (potency) per mg, calculated on the anhydrous basis. The potency of Cefalexin is expressed as mass (potency) of cefalexin ($C_{16}H_{17}N_3O_4S$).

Description Cefalexin occurs as a white to light yellowish white, crystals or crystalline powder.

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

It is hygroscopic.

Identification (1) Determine the absorption spectrum of a solution of Cefalexin (3 in 100,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelength.