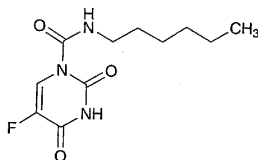


Carmofur

カルモフル



$C_{11}H_{16}FN_3O_3$: 257.26

5-Fluoro-*N*-hexyl-3,4-dihydro-2,4-dioxopyrimidine-1(2*H*)-carboxamide [61422-45-5]

Carmofur, when dried, contains not less than 98.0% of $C_{11}H_{16}FN_3O_3$.

Description Carmofur occurs as a white crystalline powder.

It is very soluble in *N,N*-dimethylformamide, freely soluble in acetic acid (100), soluble in diethyl ether, sparingly soluble in methanol and in ethanol (99.5), and practically insoluble in water.

Melting point: about 111°C (with decomposition).

Identification (1) Proceed with 5 mg of Carmofur as directed under the Oxygen Flask Combustion Method, using a mixture of 0.5 mL of 0.01 mol/L sodium hydroxide TS and 20 mL of water as the absorbing liquid, and prepare the test solution: the test solution responds to the Qualitative Tests (2) for fluoride.

(2) Determine the absorption spectrum of a solution of Carmofur in a mixture of methanol and phosphoric acid-acetic acid-boric acid buffer solution, pH 2.0, (9:1) (1 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 wavelengths.

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

Purity (1) Heavy metals—Proceed with 2.0 g of Carmofur 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—Dissolve 0.2 g of Carmofur in 10 mL of a mixture of methanol and acetic acid (100) (99:1), and use this solution as the sample solution. Pipet 1 mL of the sample solution, add a mixture of methanol and acetic acid (100) (99:1) to make exactly 500 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 15 μ L 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 toluene and acetone (5:3) 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. After exposure of the plate to bromine vapor for 30 second, spray evenly a solution of fluorescein in ethanol (95) (1 in 2500): 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, in vacuum, 50°C, 3 hours).

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

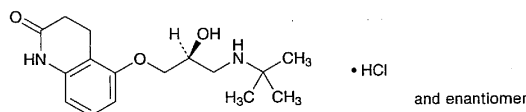
Assay Weigh accurately about 0.5 g of Carmofur, previously dried, dissolve in 20 mL of *N,N*-dimethylformamide, and titrate with 0.1 mol/L tetramethylammonium hydroxide-methanol VS until the color of the solution changes from yellow through blue-green to blue (indicator: 3 drops of thymol blue-dimethylformamide TS).

Each mL of 0.1 mol/L tetramethylammonium hydroxide-methanol VS
= 25.726 mg of $C_{11}H_{16}FN_3O_3$

Containers and storage Containers—Tight containers.

Carteolol Hydrochloride

塩酸カルテオロール



$C_{16}H_{24}N_2O_3 \cdot HCl$: 328.83

5-[(*RS*)-3-*tert*-Butylamino-2-hydroxypropyloxy]-3,4-dihydroquinolin-2(1*H*)-one monohydrochloride [51781-21-6]

Carteolol Hydrochloride, when dried, contains not less than 99.0% of $C_{16}H_{24}N_2O_3 \cdot HCl$.

Description Carteolol Hydrochloride occurs as white crystals or crystalline powder.

It is soluble in water, sparingly soluble in methanol, very slightly soluble in ethanol (95) and in acetic acid (100), and practically insoluble in diethyl ether.

The pH of a solution of Carteolol Hydrochloride (1 in 100) is between 5.0 and 6.0.

The solution of Carteolol Hydrochloride (1 in 20) shows no optical rotation.

Melting point: about 277°C (with decomposition).

Identification (1) Dissolve 0.1 g of Carteolol Hydrochloride in 5 mL of water, and add 5 drops of Reinecke salt TS: a light red precipitate is formed.

(2) Determine the absorption spectrum of a solution of Carteolol Hydrochloride (1 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 wavelengths.

(3) Determine the infrared absorption spectrum of Carteolol Hydrochloride as directed in the potassium chloride disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum: both

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 μ L 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).

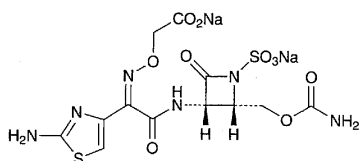
Assay Weigh accurately about 0.5 g of Carteolol Hydrochloride, previously dried, add 30 mL of acetic acid (100), dissolve by heating on a water bath, and cool. After adding 70 mL of acetic anhydride, titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination,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

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

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)[(2S,3S)-2-carbamoyloxymethyl-4-oxo-1-sulfonatoazetidino-3-ylcarbamoyl]methyleneaminooxy}acetate [86832-68-0]

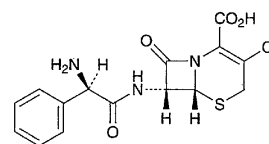
Carumonam Sodium conforms to the requirements of Carumonam Sodium in the Requirements for Antibiotic Products of Japan.

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

(6R,7R)-7-[(2R)-2-Amino-2-phenylacetyl-amino]-3-chloro-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid [53994-73-3]

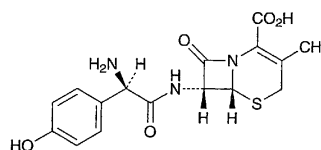
Cefaclor conforms to the requirements of Cefaclor in the Requirements for Antibiotic Products of Japan.

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

(6R,7R)-7-[(2R)-2-Amino-2-(4-hydroxyphenyl)acetyl-amino]-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 μ g (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).