

Containers and storage Containers—Hermetic containers.

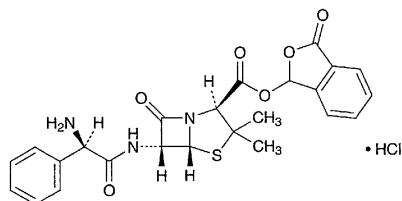
Storage—Not exceeding 5°C, and avoid freezing.

Expiration date 12 months after preparation.

Talampicillin Hydrochloride

Ampicillinphthalidyl Hydrochloride

塩酸タランピシリン



$C_{24}H_{23}N_3O_6S \cdot HCl$: 517.98

3-Oxo-1,3-dihydroisobenzofuran-1-yl (2*S*,5*R*,6*R*)-6-[(2*R*)-2-amino-2-phenylacetyl-amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate monohydrochloride [47747-56-8]

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

Description Talampicillin Hydrochloride occurs as a white to light yellowish white powder. It has a bitter taste.

It is very soluble in methanol and in ethanol (95), freely soluble in water and in ethanol (99.5), and practically insoluble in diethyl ether.

Tannic Acid

タンニン酸

Tannic Acid is the tannin usually obtained from nutgalls or rhusgalls.

Description Tannic Acid occurs as a yellowish white to light brown, amorphous powder, glistening leaflets, or spongy masses. It is odorless or has a faint, characteristic odor, and has a strongly astringent taste.

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

Identification (1) To 5 mL of a solution of Tannic Acid (1 in 400) add 2 drops of iron (III) chloride TS: a blue-black color develops. Allow the solution to stand: a blue-black precipitate is produced.

(2) To 5 mL of a solution of Tannic Acid (1 in 20) add 1 drop each of albumin TS, gelatin TS, or 1 mL of starch TS: a precipitate is produced in each solution.

Purity (1) Gum, dextrin and sucrose—Dissolve 3.0 g of Tannic Acid in 15 mL of boiling water: the solution is clear or slightly turbid. Cool, and filter the solution. To 5 mL of the filtrate add 5 mL of ethanol (95): no turbidity is

produced. Add further 3 mL of diethyl ether to this solution: no turbidity is produced.

(2) Resinous substances—To 5 mL of the filtrate obtained in (1) add 10 mL of water: no turbidity is produced.

Loss on drying Not more than 12.0% (1 g, 105°C, 2 hours).

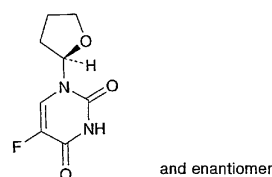
Residue on ignition Not more than 1.0% (0.5 g).

Containers and storage Containers—Tight containers.

Storage—Light-resistant.

Tegafur

テガフル



$C_8H_9FN_2O_3$: 200.17

5-Fluoro-1-[(*RS*)-tetrahydrofuran-2-yl]pyrimidine-2,4-(1*H*,3*H*)-dione [17902-23-7]

Tegafur, when dried, contains not less than 98.0% of $C_8H_9FN_2O_3$.

Description Tegafur occurs as a white, crystalline powder.

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

It dissolves in dilute sodium hydroxide TS.

Identification (1) Prepare the test solution with 0.01 g of Tegafur 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 an absorbing liquid: the test solution responds to the Qualitative Tests (2) for fluoride.

(2) Determine the absorption spectrum of a solution of Tegafur in 0.01 mol/L sodium hydroxide TS (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 Tegafur, 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.

Melting point 166–171°C

Purity (1) Clarity and color of solution—Dissolve 0.2 g of Tegafur in 10 mL of dilute sodium hydroxide TS: the solution is clear and colorless.

(2) Chloride—Dissolve 0.8 g of Tegafur in 40 mL of water by warming, cool, filter if necessary, and add 6 mL of dilute nitric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control

solution with 0.25 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.011%).

(3) Heavy metals—Dissolve 1.0 g of Tegafur in 40 mL of water by warming, cool, filter if necessary, and add 2 mL of dilute acetic acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 1.0 mL of Standard Lead Solution (not more than 10 ppm).

(4) Arsenic—To 1.0 g of Tegafur in a crucible add 10 mL of a solution of magnesium nitrate hexahydrate in ethanol (95) (1 in 10), fire the ethanol to burn, and incinerate by ignition between 750°C and 850°C. If a carbonized substance remains, moisten it with a small quantity of nitric acid, and ignite again to incinerate. After cooling, dissolve the residue in 10 mL of dilute hydrochloric acid by warming on a water bath, and perform the test with this solution using Apparatus B (not more than 2 ppm).

(5) Related substances—Dissolve 0.10 g of Tegafur in 10 mL of methanol, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add methanol to make exactly 200 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 5 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 and ethanol (95) (5:1) to a distance of about 10 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, 4 hours).

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

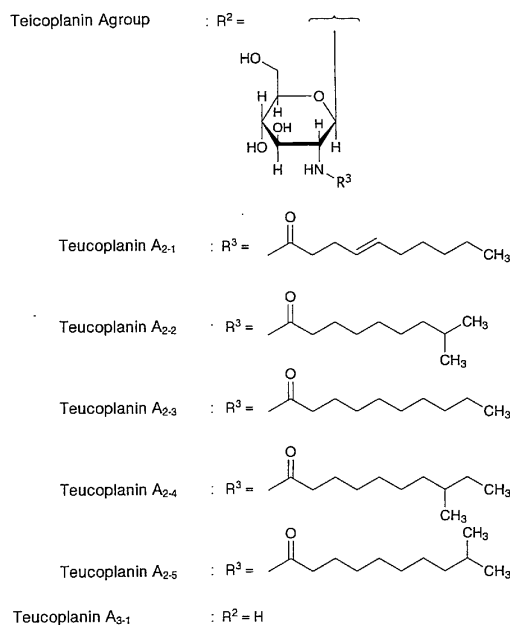
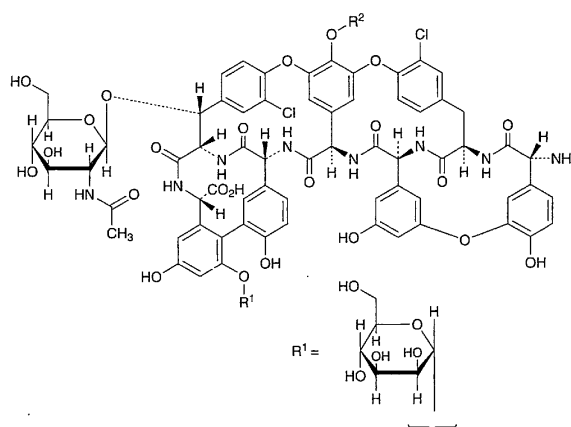
Assay Weigh accurately about 0.15 g of Tegafur, previously dried, place in an iodine bottle, dissolve in 75 mL of water, and add exactly 25 mL of 1/60 mol/L potassium bromate VS. Add rapidly 1.0 g of potassium bromide and 12 mL of hydrochloric acid, stopper the bottle tightly at once, and allow to stand for 30 minutes with occasional shaking. To this solution add 1.6 g of potassium iodide, shake gently, allow to stand for exactly 5 minutes, and titrate the liberated iodine with 0.1 mol/L sodium thiosulfate VS (indicator: 2 mL of starch TS). Perform a blank determination.

Each mL of 1/60 mol/L potassium bromate VS
= 10.008 mg of C₈H₉FN₂O₃

Containers and storage Containers—Tight containers.

Teicoplanin

テイコプラニン



Teicoplanin A₂₋₁
C₈₈H₉₅Cl₂N₉O₃₃: 1877.64
(3*S*,15*R*,18*R*,34*R*,35*S*,38*S*,48*R*,50*aR*)-34-(2-Acetylamino-2-deoxy- β -D-glucopyranosyloxy)-15-amino-22,31-dichloro-56-[2-(*Z*)-dec-4-enoylamino-2-deoxy- β -D-glucopyranosyloxy]-2,3,16,17,18,19,35,36,37,38,48,49,50,50a-tetradecahydro-6,11,40,44-tetrahydroxy-42-(α -D-mannopyranosyloxy)-2,16,36,50,51,59-hexaoxo-1*H*,15*H*,34*H*-20,23:30,33-dietheno-3,18:35,48-bis(iminomethano)-4,8:10,14:25,28:43,47-tetrametheno-28*H*-[1,14,6,22]dioxadiazacyclooctacosino[4,5-*m*][10,2,16]benzoxadiazacyclotetracosine-38-carboxylic acid [91032-34-7]

Teicoplanin A₂₋₂
C₈₈H₉₇Cl₂N₉O₃₃: 1879.66
(3*S*,15*R*,18*R*,34*R*,35*S*,38*S*,48*R*,50*aR*)-34-