782

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

C₂₄H₂₃N₃O₆S.HCl: 517.98

3-Oxo-1,3-dihydroisobenzofuran-1-yl (2S,5R,6R)-6-[(2R)-2-amino-2-phenylacetylamino]-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

テガフール

C₈H₉FN₂O₃: 200.17

5-Fluoro-1-[(RS)-tetrahydrofuran-2-yl]pyrimidine-2,4(1H,3H)-dione [I7902-23-7]

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