$C_4H_9NO_3$: 119.12
(2*S*,3*R*)-2-Amino-3-hydroxybutanoic acid [*72-19-5*]

L-Threonine, when dried, contains not less than 98.5% of $C_4H_9NO_3$.

Description L-Threonine occurs as white crystals or crystalline powder. It is odorless or has a slight, characteristic odor, and has a slightly sweet taste.

It is freely soluble in formic acid, soluble in water, and practically insoluble in ethanol (95).

Identification Determine the infrared absorption spectrum of L-Threonine, 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.

Optical rotation $[\alpha]_D^{20}$: −26.0 – −29.0° (after drying, 1.5 g, water, 25 mL, 100 mm).

pH Dissolve 0.20 g of L-Threonine in 20 mL of water: the pH of this solution is between 5.2 and 6.2.

Purity **(1)** Clarity and color of solution—Dissolve 1.0 g of L-Threonine in 20 mL of water: the solution is clear and colorless.

(2) Chloride—Perform the test with 0.5 g of L-Threonine. Prepare the control solution with 0.30 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.021%).

(3) Sulfate—Perform the test with 0.6 g of L-Threonine. Prepare the control solution with 0.35 mL of 0.005 mol/L sulfuric acid VS (not more than 0.028%).

(4) Ammonium—Perform the test with 0.25 g of L-Threonine. Prepare the control solution with 5.0 mL of Standard Ammonium Solution (not more than 0.02%).

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

(6) Arsenic—Dissolve 1.0 g of L-Threonine in 5 mL of dilute hydrochloric acid, and perform the test with this solution as the test solution using Apparatus B (not more than 2 ppm).

(7) Other amino acids—Dissolve 0.30 g of L-Threonine in 50 mL of water, and use this solution as the sample solution. Pipet 1 mL of this solution, and add water to make exactly 50 mL. Pipet 5 mL of this solution, add water to make exactly 20 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 5 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of 1-butanol, water and acetic acid (100) (3:1:1) to a distance of about 10 cm, and dry the plate at 80°C for 30 minutes. Spray evenly the plate with a solution of ninhydrin in acetone (1 in 50), and heat the plate at 80°C for 5 minutes: 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 0.20% (1 g, 105°C, 3 hours).

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

Assay Weigh accurately about 0.12 g of L-Threonine, previously dried, dissolve in 3 mL of formic acid, add 50 mL of acetic acid (100), and 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
= 11.912 mg of $C_4H_9NO_3$

Containers and storage Containers—Tight containers.

Tiaramide Hydrochloride

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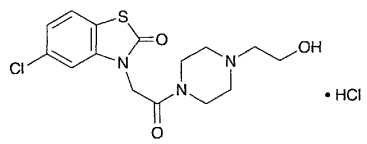

$C_{15}H_{18}ClN_3O_3S.HCl$: 392.30
5-Chloro-3-{2-[4-(2-hydroxyethyl)piperazin-1-yl]-2-oxoethyl}-3*H*-benzothiazol-2-one monohydrochloride
[*35941-71-0*]

Tiaramide Hydrochloride, when dried, contains not less than 98.5% of $C_{15}H_{18}ClN_3O_3S.HCl$.

Description Tiaramide Hydrochloride occurs as a white, crystalline powder. It is odorless.

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

The pH of a solution of Tiaramide Hydrochloride (1 in 20) is between 3.0 and 4.5.

Melting point: about 265°C (with decomposition).

Identification **(1)** Dissolve 5 mg of Tiaramide Hydrochloride in 5 mL of 0.1 mol/L hydrochloric acid TS, and add 3 drops of Dragendorff's TS: an orange precipitate is formed.

(2) Determine the infrared absorption spectrum of Tiaramide Hydrochloride, previously dried, 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.

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

Purity **(1)** Clarity and color of solution—Dissolve 0.5 g of Tiaramide Hydrochloride in 10 mL of water: the solution is clear and colorless.

(2) Heavy metals—Proceed with 2.0 g of Tiaramide 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 Tiaramide Hydrochloride according to Method 1, and perform the test using Apparatus B. In the procedure, add 20 mL of diluted hydrochloric acid (1 in 2) (not more than 2 ppm).

(4) Related substances—Dissolve 0.20 g of Tiaramide Hydrochloride in 10 mL of diluted ethanol (99.5) (7 in 10), and use this solution as the sample solution. Pipet 1 mL of the sample solution, and add diluted ethanol (99.5) (7 in 10) to make exactly 100 mL. Pipet 2 mL of this solution, add diluted ethanol (99.5) (7 in 10) 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 5 μL each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. After air-drying, immediately develop the plate with a mixture of 1-butanol, water and acetic acid (100) (4:2:1) to a distance of about 10 cm, air-dry the plate, and then dry at 100°C for 30 minutes. After cooling, examine under ultraviolet light (main wavelength: 254 nm): the spots other than the principal spot and the spot of the starting point from the sample solution are not more intense than the spot from the standard solution. Allow the plate to stand in iodine vapor for 30 minutes: the spots other than the principal spot and the spot of the starting point 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 Tiaramide Hydrochloride, previously dried, dissolve in 50 mL of a mixture of acetic anhydride and acetic acid (100) (7:3) by warming, cool, and titrate with 0.1 mol/L perchloric acid VS until the color of the solution changes from red through purple to blue-purple (indicator: 3 drops of neutral red TS). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 39.231 mg of $C_{15}H_{18}ClN_3O_3S.HCl$

Containers and storage Containers—Well-closed containers.

Ticarcillin Sodium

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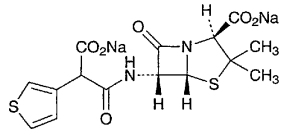

$C_{15}H_{14}N_2Na_2O_6S_2$: 428.39
Disodium (2*S*,5*R*,6*R*)-6-(2-carboxylato-2-thiophen-2-ylacetylamino)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate [*4697-14-7*]

Ticarcillin Sodium contains not less than 800 μg (potency) per mg, calculated on the anhydrous basis. The potency of Ticarcillin Sodium is expressed as mass (potency) of ticarcillin ($C_{15}H_{16}N_2O_6S_2$: 384.43).

Description Ticarcillin Sodium occurs as a white to pale yellowish white powder. It has a characteristic oder.

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

It is hygroscopic.

Identification (1) Determine the infrared absorption spectrum of Ticarcillin Sodium, previously dried in a desiccator (in vacuum, phosphorus (V) oxide, 60°C) for 2 hours, as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of Ticarcillin Sodium Reference Standard, previously dried in a desiccator (in vacuum, phosphorus (V) oxide at 60°C) for 2 hours: both spectra exhibit similar intensities of absorption at the same wave numbers.

(2) Ticarcillin Sodium responds to the Quantitative Test (1) for sodium salt.

Optical rotation $[\alpha]_D^{20}$: +170 - +190° (0.50 g calculated on the anhydrous bases, water, 50 mL, 100 mm).

pH Dissolve 1.0 g of Ticarcillin Sodium in 10 mL of water: the pH of this solution is between 5.0 and 7.5.

Purity (1) Heavy metals—Proceed with 2.0 g of Ticarcillin Sodium 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) Arsenic—Prepare the test solution with 1.0 g of Ticarcillin Sodium, according to Method 4, and perform the test using Apparatus B (not more than 2 ppm).

(3) 3-Thienylethylpenicillin sodium—When perform the test under the following condition, the value from the sample solution is not more than the value from the standard solution.

(i) Standard solution—Weigh accurately a suitable amount of 3-thienylethylpenicillin sodium, dissolve in phosphate buffer solution, pH 6.0, and add phosphate buffer solution, pH 6.0 to make a solution so that each mL contains 5.0 μg.

(ii) Sample solution—Weigh accurately a suitable amount of Ticarcillin Sodium, dissolve in phosphate buffer solution, pH 6.0, and add phosphate buffer solution, pH 6.0 to make a solution so that each mL contains 100 μg.

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

(iv) Culture medium—Use the medium i in 1) Medium for test organism [5] under (1) Agar media for seed and base layer of the Cylinder-plate method under the Microbial Assay for Antibiotics. Adjust the pH of the medium so that it will be 6.4 to 6.5 after sterilization.

(v) Developing solvent—Phosphate buffer solution, pH 6.0.

(vi) Preparation of thin-layer plate—Apply silica gel for thin-layer chromatography on a uniform thick glass plate 200 mm × 200 mm in size to make a uniform thick layer of 0.2 to 0.3 mm. Dry the plate, then dry further by heating at 105°C for 30 minutes. After cooling, develop the plate with a mixture of diethyl ether and silicone oil (19:1) for about 3 hours, and air-dry the plate.

(vii) Procedure—Designate a line about 20 mm distant from the bottom of the thin-layer plate as the starting line, spot three of 10 μL each of the sample solution and the standard solution at points on this line, separated alternately about 30 mm and 10 mm distant from the both sides, and air-dry within 15 minutes. Develop the plate at a room temperature with about 10 mm depth of the developing solvent in a vessel saturated with a vapor of the solvent to a distance of about 100 mm, and air-dry the plate. Place the plate