Taurine[1]

$C_2H_7NO_3S$: 125.15

Taurine, when dried, contains not less than 99.0 percent and not more than 101.0 percent of Taurine ($C_2H_7NO_3S$).
[by AJI TEST 17]

Taurine, when dried, contains not less than 98.0 percent and not more than 102.0 percent of Taurine ($C_2H_7NO_3S$).
[by AJI TEST 26]

Description

White crystals or crystalline powder; slightly bitter taste.

Identification

(1) Compare the infrared absorption spectrum of the sample with that of the standard by potassium bromide disc method.
(2) The retention time of major peak of the Sample solution corresponds to that of the Standard solutions, as obtained in the Assay (AJI TEST 26).

Specifications

Item	Limit	Test
State of solution (Transmittance)	Clear Not less than 95.0%	AJI TEST 2 [0.25 g in 10 mL of H_2O, spectrophotometer, 430 nm, 10 mm cell thickness]
Chloride (Cl)	Not more than 0.010%	AJI TEST 3 [1.0 g, A-1, ref: 0.28 mL of 0.01 mol/L HCl]
Ammonium (NH_4)	Not more than 0.02%	AJI TEST 4 [A-1]
Sulfate (SO_4)	Not more than 0.010%	AJI TEST 5 [1.7 g, (4), ref: 0.35 mL of 0.005 mol/L H_2SO_4]
Iron (Fe)	Not more than 10 ppm	AJI TEST 6 [0.75 g, B-1, ref: 0.75 mL of Iron Std. (0.01 mg/mL)]
Heavy metals (Pb)	Not more than 10 ppm	AJI TEST 7 [2.0 g, (1), ref: 2.0 mL of Pb Std. (0.01 mg/mL)]
Arsenic (As_2O_3)	Not more than 2 ppm	AJI TEST 8 [1.0 g, (1), ref: 2.0 mL of As_2O_3 Std.]
Related substances	Conforms[2]	AJI TEST 9 [Test sample: 50 μg, B-6-a, control; taurine 0.1 μg]
Loss on drying	Not more than 0.20%	AJI TEST 11 [1 g, at 105°C for 3 hours]
Residue on ignition (Sulfated)	Not more than 0.10%	AJI TEST 13 [1 g, at 550°C to 650°C for 3 hours]
Assay	1) 99.0 to 101.0% 2) 98.0 to 102.0%	AJI TEST 17 [Dried sample, 200 mg, (2), 50 mL of H_2O, Formaldehyde solution 5 mL, 0.1 mol/L NaOH 1 mL = 12.52 mg $C_2H_7NO_3S$] AJI TEST 26[3]

The test for Endotoxin when the material will be used for manufacturing parenteral products is as follows:

Item	Limit	Test
Endotoxin	Less than 6.0 EU/g	AJI TEST 34 [C = 1, kinetic-turbidimetric technique]

[1] This product, in terms of actual quality, conforms to USP and ChP.

[2] Any secondary spot in the chromatogram obtained from the Test Solution is less intense than the principal spot in the chromatogram obtained from the Standard Solution: the number of those spots is not more than one.

[3] Amino acid analyzer method

<Sample solution>

Weigh accurately 0.500 g of a sample and dissolve water to make exactly 100 mL. Take exactly 5mL of this solution and add water to make exactly 50 mL. Take exactly 2 mL of this solution and add 0.5 mL of 2 mol/L hydrochloric acid to make exactly 50 mL. (2 mg/dL)

<Standard solution>

Weigh accurately 50 mg of the standard and dissolve water to make exactly 250 mL. Take exactly 5mL of this solution and add 0.5 mL of 2 mol/L hydrochloric acid, and add water to make exactly 50 mL. (2 mg/dL)

<Analytical conditions>

Detection: visible absorption spectrophotometer (detection wavelength: 570 nm)

Column: 4.6 mmID×40 mm (stationary phase: Hitachi #2622SC)

Ammonia removal column: 4.6 mmID×60 mm (stationary phase: Hitachi 2650L)

Column temperature: A constant temperature of about 54˚C

Reaction temperature: A constant temperature of about 135˚C

Mobile phase: Use 4 types of citrate buffer solutions switching sequentially. After completing the analysis, regenerate the column using a regeneration buffer.

Time (min.)	PH-1(SP)* (V/V)	PH-2 (V/V)	PH-3 (V/V)	PH-4 (V/V)	PH-RG (V/V)	R1 (V/V)	R2 (V/V)	R3 (V/V)
0.0→1.2	100	0	0	0	0	50	50	0
1.2→5.0	100→35	0→65	0	0	0	50	50	0
5.0→5.1	35→0	65→0	0	0	0→100	50→0	50→0	0→100
5.1→11.6	0	0	0	0	100	0	0	100
11.6→11.7	0→100	0	0	0	100→0	0→50	0→50	100→0
11.7→27.0	100	0	0	0	0	50	50	0

＊PH-1(SP)= add 6 g of citric acid monohydrate and 130 mL of ethanol to PH-1 1 L, and make 2 L with water.

Flow rate of mobile phase: 0.40 mL/min.

Flow rate of reaction reagent: 0.35 mL/min.

<Calculation method>

Calculate for Assay of Taurine by the following equation.

Assay (%)＝$(r_u/r_s)\times(C_s/C_u)\times100$

r_u＝peak area of Taurine from the Sample solution

r_s＝peak area of Taurine from the standard solution

C_s＝concentration of Taurine in the standard solution[*1] (mg/mL)

C_u＝concentration of Taurine in the Sample solution[*2] (mg/mL)

[*1] Calculate on the purity basis.

[*2] Calculate on the dried basis.

<System suitability>
Tailing factor: Not more than 1.5
RSD: Not more than 2.0

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