Taurine[1]

$C_2H_7NO_3S$: 125.15

Taurine, when dried, contains not less than 98.0 percent and not more than 102.0 percent of Taurine ($C_2H_7NO_3S$).

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.

Specifications

Item	Limit	Test
State of solution (Transmittance)	Clear Not less than 95.0%	AJI TEST 2 [0.25g in 10mL of H_2O, spectrophotometer, 430nm, 10mm cell thickness]
Chloride (Cl)	Not more than 0.010%	AJI TEST 3 [1.0g, A-1, ref: 0.28mL of 0.01mol/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 [1.7g (4), ref: 0.35mL of 0.005mol/L H_2SO_4]
Iron (Fe)	Not more than 30ppm	AJI TEST 6 [0.25g, B-1, ref: 0.75mL of Iron Std. (0.01mg/mL)]
Heavy metals (Pb)	Not more than 10ppm	AJI TEST 7 [2.0g, (1), ref: 2.0mL of Pb Std. (0.01mg/mL)]
Arsenic (As_2O_3)	Not more than 2ppm	AJI TEST 8 [1.0g, (1), ref: 2.0mL of As_2O_3 Std.]
Related substances	Conforms[2]	AJI TEST 9 [Test sample: 50μg, B-6-a, control; taurine 0.25μg]
Loss on drying	Not more than 0.20%	AJI TEST 11 [1g, at 105°C for 3 hours]
Residue on ignition (Sulfated)	Not more than 0.10%	AJI TEST 13 [1g, at 550°C to 650°C for 3 hours]
Assay	98.0 to 102.0%	AJI TEST 26[3]

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

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

Taurine[1]

The additional test

Item	Limit	Test
Related substances	Any other impurity: Not more than 0.10% Total impurities: Not more than 0.50%	[HPLC][4]
Assay	98.5 to 101.0%	AJI TEST 15[5] [Dried sample, 200mg, B, Nitrogen determination]

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

[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 four and not more than 2.0% of the total impurities found. The limit of the total impurities is set based on USP General Notices 5.6.10.

[3] Amino acid analyzer method

<Sample solution>

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

<Standard solution>

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

<Analytical conditions>

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

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

Ammonia removal column: 4.6mmID×60mm (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 6g of citric acid monohydrate and 130mL of ethanol to PH-1 IL, and make 2L with water.

Flow rate of mobile phase: 0.40mL/min.

Flow rate of reaction reagent: 0.35mL/min.

Taurine[1]

(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 : NMT 1.5

RSD : NMT 2.0%

[4] This test is analyzed by SEKISUI MEDICAL CO., LTD.

[5] The same as foot note4.

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