L-Methionine[1]

$C_5H_{11}NO_2S$: 149.21

L-Methionine, when dried, contains not less than 99.0 percent and not more than 101.0 percent of L-Methionine ($C_5H_{11}NO_2S$).

Description

White crystals or crystalline powder; characteristic odor.
Freely soluble in formic acid, soluble in water, very slightly soluble in ethanol (95).
Dissolves in dilute hydrochloric acid.

Identification

Compare the infrared absorption spectrum of the sample with that of the standard by potassium bromide disc method.

Specifications

Item	Limit	Test
Specific rotation $[\alpha]_D^{20}$	+23.0 to +24.0°	AJI TEST 1 [Dried sample, C=2, 6mol/L HCl][2]
State of solution (Transmittance)	Clear and colorless Not less than 98.0%	AJI TEST 2 [0.5g in 20mL of H_2O, spectrophotometer, 430nm, 10mm cell thickness]
Chloride (Cl)	Not more than 0.020%	AJI TEST 3 [0.5g, A-4, ref: 0.28mL of 0.01mol/L HCl]
Ammonium (NH_4)	Not more than 0.02%	AJI TEST 4 [B-2]
Sulfate (SO_4)	Not more than 0.020%	AJI TEST 5 [0.85g, (1), ref: 0.35mL of 0.005mol/L H_2SO_4]
Iron (Fe)	Not more than 10ppm	AJI TEST 6 [0.75g, B-1, ref: 0.75mL of Iron Std. (0.01mg/mL)]
Heavy metals (Pb)	Not more than 10ppm	AJI TEST 7 [1.0g, (1), dissolve by warming, ref: 1.0mL of Pb Std. (0.01mg/mL)]
Arsenic(As_2O_3)	Not more than 1ppm	AJI TEST 8 [2.0g, (1), ref: 2.0mL of As_2O_3 Std.]
Related substances	①[3]Any unspecified impurity Not more than 0.10% Total impurities Not more than 0.30% ②[4]Methionine sulfoxide Not more than 0.10% N-Acetyl-DL-Methionine Not more than 0.20% Any unspecified impurity Not more than 0.10% Total unspecified impurities Not more than 0.30%	[HPLC][5]

L-Methionine

Specifications(cont'd)

Item	Limit	Test
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	99.0 to 101.0%	AJI TEST 14 [Dried sample, 150mg, (1), 3mL of formic acid, 50mL of acetic acid (100), 0.1mol/L $HClO_4$ 1mL=14.92mg $C_5H_{11}NO_2S$]
pH	5.6 to 6.1	AJI TEST 33 [0.5g in 20mL of H_2O]
Residual solvents Methanol	Not more than 100ppm	AJI TEST 27 [1]
Cobalt	Not more than 500ppb	ICP-MS Method

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

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

The additional test

Item	Limit	Test
Enantiomeric purity	Not more than 0.50% of D-Methionine	[HPLC][6]

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

[2] Temperature coefficient of $[\alpha]_D^t$: +0.02°

[3] HPLC(EP)

[4] HPLC(USP)

[5] Disregard limit: 0.04%

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

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