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L-Alanine			
Issued Date: Jul. 14, 2015			

L-Alanine¹

C₃H₇NO₂: 89.09

L-Alanine, when dried, contains not less than 98.5 percent and not more than 101.0 percent of L-Alanine (C₃H₇NO₂).

Description

White crystals or crystalline powder; slightly sweet taste.

Freely soluble in water and in formic acid, practically insoluble in ethanol (99.5).

Dissolves in 6mol/L 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 [α] _D ²⁰	+14.3 to +15.2°	AJI TEST 1 [Dried sample, C=10, 6mol/L HCl] ²
State of solution (Transmittance)	Clear and colorless Not less than 98.0%	AJI TEST 2 [1.0g in 10mL of H ₂ O, spectrophotometer, 430nm, 10mm cell thickness]
Chloride (Cl)	Not more than 0.020%	AJI TEST 3 [0.5g, A-1, ref: 0.28mL of 0.01mol/L HCl]
Ammonium (NH ₄)	Not more than 0.02%	AJI TEST 4 [D-1]
Sulfate (SO ₄)	Not more than 0.020%	AJI TEST 5 [0.85g, (1), ref: 0.35mL of 0.005mol/L H ₂ SO ₄]
Iron (Fe)	Not more than 10ppm	AJI TEST 6 [1.0g, A-1, ref: 1.0mL of Iron Std. (0.01mg/mL)]
Heavy metals (Pb)	Not more than 10ppm	AJI TEST 7 [1.0g, (1), ref: 1.0mL of Pb Std. (0.01mg/mL)]
Arsenic (As ₂ O ₃)	Not more than 1ppm	AJI TEST 8 [2.0g, (2), ref: 2.0mL of As ₂ O ₃ Std.]
Related substances	1)Any unspecified impurity Not more than 0.10% Total impurities Not more than 0.50% 2)Maleic acid Not more than 0.05% Malic acid Not more than 0.05% Fumaric acid Not more than 0.05% Any unspecified impurity Not more than 0.05% Total unspecified impurities Not more than 0.20%	AJI TEST 26 ³ [USP] ⁴

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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	98.5 to 101.0%	AJI TEST 14 [Dried sample, 90mg, (1), 3mL of formic acid, 50mL of acetic acid (100), 0.1mol/L HClO ₄ 1mL=8.909 mg C ₃ H ₇ NO ₂]
pH	5.7 to 6.7	AJI TEST 33 [1.0g in 20mL of H ₂ O]

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]

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

² Temperature coefficient of $[\alpha]_D^{25}$: -0.06°

³ Disregard limit: 0.05%

⁴ Disregard limit: 0.01%

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