

<b>Amino Acids Specifications / Monographs</b>	page	1 / 2
L-Histidine Monohydrochloride Monohydrate		
Issued Date: Dec, 4, 2015		

## L-Histidine Monohydrochloride Monohydrate<sup>1</sup>

C<sub>6</sub>H<sub>9</sub>N<sub>3</sub>O<sub>2</sub>·HCl·H<sub>2</sub>O: 209.63

L-Histidine Monohydrochloride Monohydrate contains not less than 99.0 percent and not more than 101.0 percent of L-Histidine Monohydrochloride (C<sub>6</sub>H<sub>9</sub>N<sub>3</sub>O<sub>2</sub>·HCl : 191.62), calculated on the anhydrous basis.

### Description

White crystals or white crystalline powder; acid taste at first, and slightly bitter taste later.

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 chloride disc method.

### Specifications

Item	Limit	Test
Specific rotation [ $\alpha$ ] <sub>D</sub> <sup>20</sup>	+9.2 to +10.6°	AJI TEST 1 [Calculated on the anhydrous basis, C=11, 6mol/L HCl]
State of solution (Transmittance)	Clear and colorless Not less than 98.0%	AJI TEST 2 [1.0g in 10mL of H <sub>2</sub> O, spectrophotometer, 430nm, 10mm cell thickness]
Chloride (Cl)	18.22 to 18.68% <sup>2</sup>	AJI TEST 3 [Calculated on the anhydrous basis, 0.8g <sup>3</sup> , B]
Ammonium (NH <sub>4</sub> )	Not more than 0.02%	AJI TEST 4 [D-1]
Sulfate (SO <sub>4</sub> )	Not more than 0.020%	AJI TEST 5 [0.85g, (1), ref: 0.35mL of 0.005mol/L H <sub>2</sub> SO <sub>4</sub> ]
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 <sub>2</sub> O <sub>3</sub> )	Not more than 1ppm	AJI TEST 8 [2.0g, (1), ref: 2.0mL of As <sub>2</sub> O <sub>3</sub> Std.]
Related substances	Any unspecified impurity Not more than 0.20% Total impurities Not more than 0.50%	AJI TEST 26 <sup>4</sup>
Water	7.2 to 10.0%	AJI TEST 12 [0.12g, methanol for Karl Fischer method, A, 30 minutes]
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 [Calculated on the anhydrous basis, 100mg, (3), 3mL of formic acid, 0.1mol/L HClO <sub>4</sub> 1mL=9.581mg C <sub>6</sub> H <sub>9</sub> N <sub>3</sub> O <sub>2</sub> ·HCl]

<b>Amino Acids Specifications / Monographs</b>	page	2 / 2
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### Specifications (cont'd)

Item	Limit	Test
pH	3.5 to 4.5	AJI TEST 33 [1.0g in 10mL of H <sub>2</sub> 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]

<sup>1</sup> This product, in terms of actual quality, conforms to EP and JP.

<sup>2</sup> Chloride (Cl) as L-HisHCl.

<sup>3</sup> Weigh accurately 0.8g of the sample and add water to make exactly 50mL.

<sup>4</sup> Disregard limit: 0.05%

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