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L-Histidine Monohydrochloride Monohydrate		
Issued Date: Aug. 8, 2025		

## 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.

L-Histidine Monohydrochloride Monohydrate contains not less than 99.0 percent and not more than 101.0 percent of L-Histidine Monohydrochloride Monohydrate (C<sub>6</sub>H<sub>9</sub>N<sub>3</sub>O<sub>2</sub>·HCl·H<sub>2</sub>O: 209.63), calculated on the dried 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

- 1) Compare the infrared absorption spectrum of the sample with that of the standard by potassium chloride disc method.
- 2) Compare the position and ninhydrin reaction of the test solution with that of the reference solution by chromatographic separation technique.

### Specifications

Item	Limit	Test
Specific rotation [ $\alpha$ ] <sub>D</sub> <sup>20</sup>	1) +9.2 to +10.6°	AJI TEST 1 [Calculated on the anhydrous basis, C = 11, 6 mol/L HCl]
	2) +8.8 to +10.2°	AJI TEST 1 [Calculated on the dried basis, C = 11, 6 mol/L HCl]
State of solution (Transmittance)	Clear and colorless Not less than 98.0%	AJI TEST 2 [1.0 g in 10 mL of H <sub>2</sub> O, spectrophotometer, 430 nm, 10 mm cell thickness]
Chloride (Cl)	1) 18.22 to 18.68% <sup>2</sup>	AJI TEST 3 [Calculated on the anhydrous basis, 0.8 g <sup>3</sup> , B]
	2) 16.7 to 17.1% <sup>4</sup>	AJI TEST 3 [Calculated on the dried basis, 0.8 g <sup>5</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 [0.85 g, (1), ref: 0.35 mL of 0.005 mol/L H <sub>2</sub> SO <sub>4</sub> ]
Iron (Fe)	Not more than 10 ppm	AJI TEST 6 [1.0 g, A-1, ref: 1.0 mL of Iron Std. (0.01 mg/mL)]
Heavy metals (Pb)	Not more than 10 ppm	AJI TEST 7 [1.0 g, (1), ref: 1.0 mL of Pb Std. (0.01 mg/mL)]
Arsenic (As <sub>2</sub> O <sub>3</sub> )	Not more than 1 ppm	AJI TEST 8 [2.0 g, (1), ref: 2.0 mL of As <sub>2</sub> O <sub>3</sub> Std.]

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Specifications (cont'd)

Item	Limit	Test
Related substances	1) Conforms  2) Any unspecified impurity Not more than 0.20% Total impurities Not more than 0.50%	[ChP]  AJI TEST 26 <sup>6</sup>
Loss on drying	Not more than 0.20%	AJI TEST 11 [1 g, at 105°C for 3 hours]
Water	7.2 to 10.0%	AJI TEST 12 [0.12 g, methanol for Karl Fischer method, A, 30 minutes]
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) 99.0 to 101.0%	AJI TEST 14 [Calculated on the anhydrous basis, 100 mg, (3), 3 mL of formic acid, 0.1 mol/L HClO <sub>4</sub> 1 mL = 9.581 mg C <sub>6</sub> H <sub>9</sub> N <sub>3</sub> O <sub>2</sub> ·HCl]  AJI TEST 14 [Calculated on the dried basis, 100 mg, (3), 3 mL of formic acid, 0.1 mol/L HClO <sub>4</sub> 1 mL = 10.48 mg C <sub>6</sub> H <sub>9</sub> N <sub>3</sub> O <sub>2</sub> ·HCl·H <sub>2</sub> O]
pH	3.5 to 4.5	AJI TEST 33 [1.0 g in 10 mL of H <sub>2</sub> O]

The following test item is added for parenteral products:

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

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

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

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

<sup>4</sup> Chloride (Cl) as L-HisHCl·H<sub>2</sub>O.

<sup>5</sup> The same as foot note 3.

<sup>6</sup> Disregard limit: 0.05%

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