

L-Histidine Monohydrochloride, F.C.C.  
Multi-Compendial



Material No.: 2081-06  
Batch No.: 0000107468  
Manufactured Date: 2014/04/10  
Retest Date: 2019/04/09

## Certificate of Analysis

Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications, Meets F.C.C. Requirements, Meets J.P. Chemical Specifications,  
GMP Manufactured Product, Food GMP Manufactured Product

Test	Specification	Result
FCC - Assay (C <sub>6</sub> H <sub>9</sub> N <sub>3</sub> O <sub>2</sub> · HCl) (dried basis)	98.5 - 101.5 %	100.7
FCC - Identification	Passes Test	PT
FCC - Lead (Pb)	<= 5 mg/kg	< 5
FCC - Loss on Drying at 105°C	<= 0.3 %	< 0.3
FCC - Residue after Ignition	<= 0.1 %	< 0.1
FCC - Specific Rotation [A] <sup>20</sup> <sup>AD</sup> (+)	8.5 - 10.5 Degree	9.1
EP/BP - Assay (C <sub>6</sub> H <sub>9</sub> N <sub>3</sub> O <sub>2</sub> · HCl) (dried basis)	98.5 - 101.0 %	100.3
EP/BP - Identification A	Passes Test	PT
EP/BP - Identification B	Passes Test	PT
EP/BP - Identification C	Passes Test	PT
EP/BP - Identification F	Passes Test	PT
EP/BP - Appearance of Solution	Passes Test	PT
EP/BP - pH	3.0 - 5.0	4.0
EP/BP - Specific Rotation [A] <sup>20</sup> <sup>AD</sup> (+)	9.2 - 10.6 Degree	9.8
EP/BP-Ninhydrin-Positive Substances-Each	<= 0.2 %	< 0.2
EP/BP-Ninhydrin-Positive Substances-Total Impurities	<= 0.5 %	< 0.5
EP/BP - Sulfate (SO <sub>4</sub> )	<= 300 ppm	< 300
EP/BP - Ammonium (NH <sub>4</sub> )	<= 0.02 %	< 0.02
EP/BP - Heavy Metals (as Pb)	<= 10 ppm	< 10
EP/BP - Iron (Fe)	<= 10 ppm	< 10
EP/BP - Loss on Drying at 150°C	7.0 - 10.0 %	8.7
EP/BP - Ash (sulfated)	<= 0.1 %	< 0.1
JP - Identification	Passes Test	PT

Test	Specification	Result
JP - Optical Rotation (+)	9.2 - 10.6	9.8
JP - pH	3.5 - 4.5	4.1
JP - Clarity and Color of Solution	Passes Test	PT
JP - Sulfate (SO <sub>4</sub> )	<= 0.028 %	< 0.028
JP - Ammonium (NH <sub>4</sub> )	<= 0.02 %	< 0.02
JP - Heavy Metals (as Pb)	<= 10 ppm	< 10
JP - Iron (Fe)	<= 10 ppm	< 10
JP - Related Substances	Passes Test	PT
JP - Water	7.2 - 10.0 %	8.8
JP - Residue on Ignition	<= 0.1 %	< 0.1
JP - Assay (anhydrous basis)	99.0 - 101.0 %	100.9
Endotoxin Concentration, IU/mg ,For Information Only		< 0.01

Bulk Food Chemical

Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

No Class 1,2,3 or other solvents are used or produced in the manufacturing or purification of the product.

Metallic Residues: No metal catalysts or metal reagents, as defined by EMA Guideline EMEA/CHMP/SWP/4446/2000 , are used in the production of this material.

Storage Conditions: Store in airtight container.

Country of Origin: JP

Packaging Site: Paris Mfg Ctr & DC

Manufacturer: P0062001

Manufacturer source batch: 140414



Phillipsburg, NJ 9001:2008, 14001:2004, FSSC 22000  
 Paris, KY 9001:2008  
 Mexico City, Mexico 9001:2008  
 Deventer, The Netherlands 9001:2008, 14001:2004, 13485:2003  
 Gliwice, Poland 9001:2008, 17025:2005  
 Selangor, Malaysia 9001:2008  
 Dehradun, India, 9001:2008, 14001:2004, 13485:2003  
 Mumbai, India, 9001:2008, 17025:2005  
 Panoli, India 9001:2008

Richard M Siberski  
 Vice President Global Quality

For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.573.2600  
 Avantor™ Performance Materials Inc.

3477 Corporate Parkway, Suite #200, Center Valley, PA 18034. U.S.A. Phone: 610.573.2600 . Fax: 610.573.2610