L-Histidine
Multi-Compendial

Material No.: 4935-06
Batch No.: 0000267727
Manufactured Date: 2020/01/13
Expiration Date: 2023/01/12
Release Date: 2020/09/22
Revision No: 1

Certificate of Analysis

Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications, Meets J.P. Chemical Specifications, Meets U.S.P Requirements, GMP Manufactured Product

Test	Specification	Result
USP - Assay ($C_6H_9N_3O_2$) (dried basis)	98.5 - 101.5 %	99.2
USP - Identification	Passes Test	PT
USP - Specific Rotation [Å]^{25} ^D (+)	12.6 - 14.0 Degree	13.2
USP - pH	7.0 - 8.5	7.7
USP - Loss on Drying at 105°C	<= 0.2 %	< 0.1
USP - Residue on Ignition	<= 0.4 %	< 0.1
USP - Chloride (Cl)	<= 0.05 %	< 0.05
USP - Sulfate (SO_4)	<= 0.03 %	< 0.03
USP - Iron (Fe)	<= 0.003 %	< 0.003
USP - Related Compounds - Individual Impurities	<= 0.5 %	< 0.5
USP - Related Compounds - Total Impurities	<= 2.0 %	< 2.0
EP/BP - Assay ($C_6H_9N_3O_2$) (dried basis)	98.5 - 101.0 %	100.0
EP/BP - Identification A	Passes Test	PT
EP/BP - Identification B	Passes Test	PT
EP/BP - Appearance of Solution	Passes Test	PT
EP/BP - Specific Rotation [Å]^{20}^D (+)	11.4 - 12.4 Degree	12.0
EP/BP-Ninhydrin-Positive Substances-Each	<= 0.2 %	< 0.1
EP/BP-Ninhydrin-Positive Substances-Total Impurities	<= 0.5 %	< 0.1
EP/BP - Chloride (Cl)	<= 200 ppm	< 200
EP/BP - Sulfate (SO_4)	<= 300 ppm	< 300
EP/BP - Ammonium (NH_4)	<= 0.02 %	< 0.02
EP/BP - Iron (Fe)	<= 10 ppm	< 10
EP/BP - Loss on Drying	<= 0.5 %	< 0.1

For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.386.1700
Avantor Performance Materials, LLC
100 Matsonford Rd, Suite 200, Radnor, PA 19087. U.S.A. Phone: 610.386.1700

Material No.: 4935-06
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Test	Specification	Result
EP/BP - Ash (sulfated)	<= 0.1 %	< 0.1
Endotoxin Concentration, IU/mg ,For Information Only		< 0.0030
JP - Assay ($C_6H_9N_3O_2$) (dried basis)	99.0 - 101.0 %	99.2
JP - Ammonium (NH_4)	<= 0.02 %	< 0.02
JP - Chloride (Cl)	<= 0.021 %	< 0.021
JP - Clarity and Color of Solution	Passes Test	PT
JP - Heavy Metals (as Pb)	<= 10 ppm	< 10
JP - Iron (Fe)	<= 10 ppm	< 10
JP - Identification	Passes Test	PT
JP - Loss on Drying at 105°C	<= 0.3 %	< 0.1
JP- Optical Rotation [Å]²°^D (+)	11.8 - 12.8 Degree	12.4
JP - Related Substances	Passes Test	PT
JP - pH	7.0 - 8.5	7.7
JP - Residue on Ignition	<= 0.1 %	<0.01
JP - Sulfate (SO_4)	<= 0.028 %	< 0.028

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.

Elemental Impurities (USP (232), EP 5.20) - Information on elemental impurities for this product is available on the associated Product Regulatory Data Sheet and elemental impurity profile report.

Country of Origin:	CN
Packaging Site:	Paris Mfg Ctr & DC
Manufacturer:	P0005111
Manufacturer source batch:	20011729

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