

Material No.: 4942-06
Batch No.: 24E2361036
Manufactured Date: 2023-01-17
Expiration Date: 2026-01-16
Release Date: 2024-06-14
Revision No.: 0

Certificate of Analysis

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

Test	Specification	Result
EP/BP – Assay (C ₆ H ₉ N ₃ O ₂ · HCl) (dried basis)	98.5 – 101.0 %	99.8 %
EP/BP – Identification A	Passes Test	Passes Test
EP/BP – Identification B	Passes Test	Passes Test
EP/BP – Identification C	Passes Test	Passes Test
EP/BP – Identification F	Passes Test	Passes Test
EP/BP – Appearance of Solution	Passes Test	Passes Test
EP/BP – pH	3.0 – 5.0	3.9
EP/BP – Specific Rotation [α] _D ²⁰ (+)	9.2 – 10.6 °	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 ₄)	≤ 300 ppm	< 300 ppm
EP/BP – Ammonium (NH ₄)	≤ 0.02 %	< 0.02 %
EP/BP – Iron (Fe)	≤ 10 ppm	< 10 ppm
EP/BP – Loss on Drying at 150°C	7.0 – 10.0 %	8.3 %
EP/BP – Ash (sulfated)	≤ 0.1 %	< 0.1 %
JP – Identification	Passes Test	Passes Test
JP – Optical Rotation (+)	9.2 – 10.6	9.8
JP – pH	3.5 – 4.5	3.9
JP – Clarity and Color of Solution	Passes Test	Passes Test
JP – Sulfate (SO ₄)	≤ 0.028 %	< 0.028 %
JP – Ammonium (NH ₄)	≤ 0.02 %	< 0.02 %
JP – Iron (Fe)	≤ 10 ppm	< 10 ppm
JP – Related Substances	Passes Test	Passes Test
JP – Water	7.2 – 10.0 %	8.1 %
JP – Residue on Ignition	≤ 0.10 %	< 0.10 %
JP – Assay (anhydrous basis)	99.0 – 101.0 %	100.3 %
Endotoxin Concentration, IU/mg ,For Information Only		< 0.003

L-Histidine Monohydrochloride
Multi-Compendial



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GMP Manufactured Product
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 Condition: Store in airtight container.

Country of Origin: China
Packaging Site: Paris Mfg Ctr & DC
Manufacturer: P0005111
Manufacturer source batch: 23010817

Michelle Bales
Sr. Manager, Quality Assurance

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