

Material No.: 4935-06
Batch No.: 24C2261064
Manufactured Date: 2023-10-29
Expiration Date: 2026-10-28
Release Date: 2024-04-12
Revision No.: 0

Certificate of Analysis

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

Test	Specification	Result
USP – Assay (C ₆ H ₉ N ₃ O ₂) (dried basis)	98.5 – 101.5 %	100.5 %
USP – Identification	Passes Test	Passes Test
USP – Specific Rotation [α] _D ²⁵ (+)	12.6 – 14.0 °	13.0 °
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 ₆ H ₉ N ₃ O ₂) (dried basis)	98.5 – 101.0 %	99.7 %
EP/BP – Identification A	Passes Test	Passes Test
EP/BP – Identification B	Passes Test	Passes Test
EP/BP – Appearance of Solution	Passes Test	Passes Test
EP/BP – Specific Rotation [α] _D ²⁰ (+)	11.4 – 12.4 °	11.8 °
EP/BP–Ninhydrin–Positive Substances–Each	≤ 0.2 %	< 0.2 %
EP/BP–Ninhydrin–Positive Substances–Total Impurities	≤ 0.5 %	< 0.5 %
EP/BP – Chloride (Cl)	≤ 200 ppm	< 200 ppm
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	≤ 0.5 %	< 0.1 %
EP/BP – Ash (sulfated)	≤ 0.1 %	< 0.1 %
Endotoxin Concentration, IU/mg ,For Information Only		< 0.001
JP – Assay (C ₆ H ₉ N ₃ O ₂) (dried basis)	99.0 – 101.0 %	100.5 %
JP – Ammonium (NH ₄)	≤ 0.02 %	< 0.02 %
JP – Chloride (Cl)	≤ 0.021 %	< 0.021 %

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L-Histidine
Multi-Compendial



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Test	Specification	Result
JP - Clarity and Color of Solution	Passes Test	Passes Test
JP - Heavy Metals (as Pb)	≤ 10 ppm	< 10 ppm
JP - Iron (Fe)	≤ 10 ppm	< 10 ppm
JP - Identification	Passes Test	Passes Test
JP - Loss on Drying at 105°C	≤ 0.30 %	< 0.10 %
JP- Optical Rotation [α] ²⁰ _D (+)	11.8 - 12.8 °	12.4 °
JP - Related Substances	Passes Test	Passes Test
JP - pH	7.0 - 8.5	7.7
JP - Residue on Ignition	≤ 0.1 %	< 0.1 %
JP - Sulfate (SO ₄)	≤ 0.028 %	< 0.028 %

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.

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.

Storage Condition: Store in airtight container.

Country of Origin: China

Packaging Site: Paris Mfg Ctr & DC

Manufacturer: P0005111

Manufacturer source batch: 23102660

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

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