

Material No.: 4932-06
Batch No.: 24D3061034
Manufactured Date: 2023-05-18
Expiration Date: 2026-05-17
Release Date: 2024-05-10
Revision No.: 0

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 ₆ H ₁₄ N ₄ O ₂) (dried basis)	98.5 – 101.5 %	99.8 %
USP – Identification	Passes Test	Passes Test
USP – Specific Rotation [A] ²⁵ ^D (+)	26.3 – 27.7 °	27.2 °
USP – Loss on Drying at 105°C	≤ 0.5 %	< 0.1 %
USP – Chloride (Cl)	≤ 0.05 %	< 0.05 %
USP – Residue on Ignition	≤ 0.3 %	< 0.1 %
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 ₁₄ N ₄ O ₂) (dried basis)	98.5 – 101.0 %	99.8 %
EP/BP – Identification A	Passes Test	Passes Test
EP/BP – Identification C	Passes Test	Passes Test
EP/BP – Appearance of Solution	Passes Test	Passes Test
EP/BP – Specific Rotation [A] ²⁰ ^D (+)	25.5 – 28.5 °	28.0 °
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 %
JP – Identification	Passes Test	Passes Test
JP – Optical rotation, 20° C (+)	26.9 – 27.9 °	27.6 °
JP – pH (1:10)	10.5 – 12.0	11.2
JP – Clarity and Color of Solution	Passes Test	Passes Test
JP – Chloride (Cl)	≤ 0.021 %	< 0.021 %

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L-Arginine
Multi-Compendial



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Test	Specification	Result
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 - Loss on Drying at 105°C	≤ 0.30 %	< 0.10 %
JP - Residue after Ignition	≤ 0.1 %	< 0.1 %
JP - Assay (C ₆ H ₁₄ N ₄ O ₂)(dried basis)	98.5 - 101.0 %	99.8 %
Endotoxin Concentration, IU/mg, For Information Only		< 0.003

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: Preserve in well-closed containers.

Country of Origin: China

Packaging Site: Paris Mfg Ctr & DC

Manufacturer: P0005111

Manufacturer source batch: 23053917

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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