

Material No.: 4930-06
Batch No.: 24C0561033
Manufactured Date: 2023-02-01
Expiration Date: 2026-01-31
Release Date: 2024-03-25
Revision No.: 0

Certificate of Analysis

Meets B.P. Chemical Specifications, Meets ChP 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 · HCl) (dried basis)	98.5 – 101.5 %	100.4 %
USP – Identification	Passes Test	Passes Test
USP – Specific Rotation [A] ²⁰ ∧D (+)	21.4 – 23.6 °	22.4 °
USP – Loss on Drying at 105°C	≤ 0.2 %	< 0.1 %
USP – Residue on Ignition	≤ 0.1 %	< 0.1 %
USP – Sulfate (SO ₄)	≤ 0.03 %	< 0.03 %
USP – Related Compounds – Individual Impurities	≤ 0.5 %	< 0.5 %
USP – Related Compounds – Total Impurities	≤ 2.0 %	< 2.0 %
USP – Chloride (Cl)	16.5 – 17.1 %	17.0 %
EP/BP – Assay (C ₆ H ₁₄ N ₄ O ₂ · HCl) (dried basis)	98.5 – 101.0 %	100.1 %
EP/BP – Identification A	Passes Test	Passes Test
EP/BP – Identification B	Passes Test	Passes Test
EP/BP – Identification E	Passes Test	Passes Test
EP/BP – Appearance of Solution	Passes Test	Passes Test
EP/BP – Specific Rotation [A] ²⁰ ∧D (+)	21.0 – 23.5 °	22.6 °
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	≤ 0.5 %	< 0.1 %
EP/BP – Ash (sulfated)	≤ 0.1 %	< 0.1 %
JP – Assay (C ₆ H ₁₄ N ₄ O ₂ · HCl) (dried basis)	98.5 – 101.0 %	99.9 %
JP – Identification	Passes Test	Passes Test
JP – Optical Rotation (+)	21.5 – 23.5 °	22.5 °
JP – pH (1 in 10)	4.7 – 6.2	5.6
JP – Clarity and Color of Solution	Passes Test	Passes Test
JP – Sulfate (SO ₄)	≤ 0.028 %	< 0.028 %

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Test	Specification	Result
JP – Ammonium (NH ₄)	≤ 0.02 %	< 0.02 %
JP – Related Substances	Passes Test	Passes Test
JP – Loss on Drying at 105°C	≤ 0.20 %	0.01 %
JP – Residue after Ignition	≤ 0.10 %	0.04 %
Endotoxin Concentration, IU/mg, For Information Only		< 0.003
ChP – Proteins	Passes Test	Passes Test
ChP – Sulfates	≤ 0.02 %	< 0.02 %
ChP – Other amino acids (TLC)(≤0.2%, one spot only)	Passes Test	Passes Test
ChP – Phosphates	≤ 0.02 %	< 0.02 %
ChP – Residue on ignition	≤ 0.1 %	< 0.1 %
ChP – Identification 1 (TLC)	Passes Test	Passes Test
ChP – Assay (dried basis)	98.5 – 101.0 %	100.4 %
ChP – Iron	≤ 0.001 %	< 0.001 %
ChP – Ammonium	≤ 0.02 %	< 0.02 %
ChP – Loss on drying @ 105 °C	≤ 0.2 %	< 0.2 %
ChP – Arsenic	≤ 0.0001 %	< 0.0001 %
ChP – Specific Rotation @ 20 °C (+)	21.5 – 23.5	22.4
ChP – Chloride Content	16.5 – 17.1 %	17.0 %
ChP – Heavy metals	≤ 0.001 %	< 0.001 %
ChP – Transmittance of solution	≥ 98.0 %	99.7 %
ChP – Identification 2 (IR)	Passes Test	Passes Test

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L-Arginine Hydrochloride
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.
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 well-closed, light-resistant containers

Country of Origin: China
Packaging Site: Paris Mfg Ctr & DC
Manufacturer: P0005111
Manufacturer source batch: 23012211

Michelle Bales
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For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.386.1700
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