



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

EP/BP – Identification A Passes Test Passes Test EP/BP – Identification B Passes Test EP/BP – Identification C Passes Test EP/BP – Identification F Passes Test EP/BP – Appearance of Solution Passes Test EP/BP – Appearance of Solution Passes Test EP/BP – Appearance of Solution Passes Test EP/BP – BH Superance of Solution EP/BP – Specific Rotation [Å]²°^D (+) Passes Test EP/BP – Specific Rotation [Å]²°^D (+) Passes Test EP/BP-Ninhydrin-Positive Substances-Each EP/BP-Ninhydrin-Positive Substances-Total Impurities Substances – Total Impurities EP/BP – Sulfate (SO₄) EP/BP – Sulfate (SO₄) EP/BP – Ammonium (NH₄) Superance Su	Test	Specification	Result
EP/BP - Identification B Passes Test Pass	EP/BP – Assay (C₀H₀N₃O₂·HCl) (dried basis)	98.5 - 101.0 %	99.8 %
EP/BP - Identification C EP/BP - Identification C EP/BP - Identification F Passes Test Passes Test EP/BP - Appearance of Solution Passes Test EP/BP - Appearance of Solution Passes Test EP/BP - PH 3.0 - 5.0 3.9 EP/BP - Specific Rotation [Å]²°^D (+) 9.2 - 10.6 ° 9.8 ° EP/BP-Ninhydrin-Positive Substances-Each EP/BP-Ninhydrin-Positive Substances-Total Impurities EP/BP-Ninhydrin-Positive Substances-Total Impurities EP/BP - Sulfate (SO4) EP/BP - Ammonium (NH4) SO.02 % EP/BP - Iron (Fe) SID ppm	EP/BP - Identification A	Passes Test	Passes Test
EP/BP - Identification F EP/BP - Appearance of Solution Passes Test EP/BP - Appearance of Solution Passes Test Passes Test EP/BP - PH 3.0 - 5.0 3.9 EP/BP - Specific Rotation [Å]²°^D (+) 9.2 - 10.6 ° 9.8 ° EP/BP-Ninhydrin-Positive Substances-Each ≤ 0.2 % EP/BP-Ninhydrin-Positive Substances-Total Impurities ≤ 0.5 % EP/BP-Ninhydrin-Positive Substances-Total Impurities ≤ 0.5 % EP/BP - Sulfate (SO₄) ≤ 300 ppm ≤ 300 ppm ∈ P/BP - Ammonium (NH₄) ≤ 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) □ P - Identification □ Passes Test □ Passe	EP/BP – Identification B	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 [Å]²°^D (+) 9.2 - 10.6 ° 9.8 ° EP/BP-Ninhydrin-Positive Substances-Each ≤ 0.2 % < 0.2 %	EP/BP – Identification C	Passes Test	Passes Test
EP/BP − pH EP/BP − Specific Rotation [Å]²°^D (+) EP/BP − Specific Rotation [Å]²°^D (+) EP/BP-Ninhydrin-Positive Substances-Each EP/BP-Ninhydrin-Positive Substances-Total Impurities EP/BP-Ninhydrin-Positive Substances-Total Impurities EP/BP-Sulfate (SO₄) EP/BP − Sulfate (SO₄) EP/BP − Ammonium (NH₄) ≤ 0.02 % EP/BP − Iron (Fe) EP/BP − Loss on Drying at 150°C 7.0 − 10.0 % 8.3 % EP/BP − Ash (sulfated) EP/BP − Ash (sulfated) EP/BP − Ash (sulfated) EP/BP − Optical Rotation (+) EP/BP − Description Passes Test Passes Tes	EP/BP – Identification F	Passes Test	Passes Test
EP/BP – Specific Rotation [Å]²°^D (+) EP/BP – Specific Rotation [Å]²°^D (+) EP/BP-Ninhydrin-Positive Substances-Each ≤ 0.2 % EP/BP-Ninhydrin-Positive Substances-Total Impurities EP/BP – Sulfate (SO4) EP/BP – Sulfate (SO4) EP/BP – Ammonium (NH4) ≤ 0.02 % EP/BP – Iron (Fe) EP/BP – Loss on Drying at 150°C 7.0 – 10.0 % 8.3 % EP/BP – Ash (sulfated) SP – Identification Passes Test	EP/BP - Appearance of Solution	Passes Test	Passes Test
EP/BP-Ninhydrin-Positive Substances-Each ≤ 0.2 % < 0.2 % < 0.5 % < 0.5 % < 0.5 % < 0.5 % < 0.5 % < 0.5 % < 0.5 % < 0.5 % < 0.5 % < 0.5 % < 0.5 % < 0.05 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.04 % < 0.1 % < 0.1 % < 0.1 % < 0.1 % < 0.1 % < 0.1 % < 0.1 % < 0.1 % < 0.1 % < 0.1 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % <	EP/BP - pH	3.0 - 5.0	3.9
EP/BP-Ninhydrin-Positive Substances-Total Impurities ≤ 0.5 % < 0.5 % < 0.5 % < 0.5 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.01 % < 0.1 % < 0.1 % < 0.1 % < 0.1 % < 0.1 % < 0.1 % < 0.1 % < 0.1 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02 % < 0.02	EP/BP – Specific Rotation [Å]2°^D (+)	9.2 - 10.6 °	9.8 °
EP/BP - Sulfate (SO ₄) EP/BP - Ammonium (NH ₄) EP/BP - Iron (Fe) EP/BP - Loss on Drying at 150°C EP/BP - Ash (sulfated) JP - Identification Passes Test JP - Optical Rotation (+) JP - Clarity and Color of Solution JP - Sulfate (SO ₄) JP - Sulfate (SO ₄) JP - Asmonium (NH ₄) JP - Iron (Fe) Solution Passes Test Passes Test	EP/BP-Ninhydrin-Positive Substances-Each	≤ 0.2 %	< 0.2 %
EP/BP - Ammonium (NH4) ≤ 0.02 % < 0.02 %	EP/BP-Ninhydrin-Positive Substances-Total Impurities	≤ 0.5 %	< 0.5 %
EP/BP - Iron (Fe) ≤ 10 ppm < 10 ppm EP/BP - Loss on Drying at 150°C	EP/BP - Sulfate (SO ₄)	≤ 300 ppm	< 300 ppm
EP/BP - Loss on Drying at 150°C $7.0 - 10.0\%$ 8.3% EP/BP - Ash (sulfated) $\leq 0.1\%$ $< 0.1\%$ 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 (SO4) $\leq 0.028\%$ $< 0.028\%$ JP - Ammonium (NH4) $\leq 0.02\%$ $< 0.02\%$ JP - Iron (Fe) ≤ 10 ppm < 10 ppm JP - Related Substances Passes Test Passes Test JP - Water $7.2 - 10.0\%$ $< 1.0\%$ JP - Residue on Ignition $\leq 0.10\%$ $< 0.10\%$ JP - Assay (anhydrous basis) $99.0 - 101.0\%$ 100.3%	EP/BP – Ammonium (NH ₄)	≤ 0.02 %	< 0.02 %
EP/BP - Ash (sulfated) $\leq 0.1 \%$ $< 0.1 \%$ JP - IdentificationPasses TestPasses TestJP - Optical Rotation (+) $9.2 - 10.6$ 9.8 JP - PH $3.5 - 4.5$ 3.9 JP - Clarity and Color of SolutionPasses TestPasses TestJP - Sulfate (SO4) $\leq 0.028 \%$ $< 0.028 \%$ JP - Ammonium (NH4) $\leq 0.02 \%$ $< 0.02 \%$ JP - Iron (Fe) $\leq 10 \mathrm{ppm}$ $< 10 \mathrm{ppm}$ JP - Related SubstancesPasses TestPasses TestJP - Water $7.2 - 10.0 \%$ 8.1% JP - Residue on Ignition $\leq 0.10 \%$ $< 0.10 \%$ JP - Assay (anhydrous basis) $99.0 - 101.0 \%$ 100.3%	EP/BP – Iron (Fe)	≤ 10 ppm	< 10 ppm
$ Passes Test & Passes Test \\ PP - Optical Rotation (+) & 9.2 - 10.6 & 9.8 \\ PP - DPH & 3.5 - 4.5 & 3.9 \\ PP - Clarity and Color of Solution & Passes Test & Passes Test \\ PP - Sulfate (SO4) & ≤ 0.028 % & < 0.028 % \\ PP - Ammonium (NH4) & ≤ 0.02 % & < 0.02 % \\ PP - Iron (Fe) & ≤ 10 ppm & < 10 ppm \\ PP - Related Substances & Passes Test & Passes Test \\ PP - Water & 7.2 - 10.0 % & 8.1 % \\ PP - Residue on Ignition & ≤ 0.10 % & < 0.10 % \\ PP - Assay (anhydrous basis) & 99.0 - 101.0 % & 100.3 % $	EP/BP - Loss on Drying at 150°C	7.0 - 10.0 %	8.3 %
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 (SO4) $\leq 0.028\%$ $< 0.028\%$ JP - Ammonium (NH4) $\leq 0.02\%$ $< 0.02\%$ JP - Iron (Fe) $\leq 10 \text{ ppm}$ $< 10 \text{ ppm}$ JP - Related Substances Passes Test Passes Test JP - Water $7.2 - 10.0\%$ 8.1% JP - Residue on Ignition $\leq 0.10\%$ $< 0.10\%$ JP - Assay (anhydrous basis) $99.0 - 101.0\%$ 100.3%	EP/BP – Ash (sulfated)	≤ 0.1 %	< 0.1 %
$\begin{array}{llllllllllllllllllllllllllllllllllll$	JP – Identification	Passes Test	Passes Test
JP - Clarity and Color of Solution JP - Sulfate (SO ₄) JP - Sulfate (SO ₄) JP - Ammonium (NH ₄) JP - Iron (Fe) JP - Iron (Fe) JP - Related Substances JP - Water JP - Water JP - Residue on Ignition JP - Assay (anhydrous basis) JP - Assay (anhydrous basis) JP - Assay (anhydrous basis) JP - Residue on Ignition JP - Assay (anhydrous basis) JP - Assay (anhydrous basis)	JP - Optical Rotation (+)	9.2 - 10.6	9.8
$\begin{array}{llllllllllllllllllllllllllllllllllll$	JP – pH	3.5 - 4.5	3.9
JP - Ammonium (NH ₄) $\leq 0.02 \%$ $< 0.02 \%$ $\leq 10 \mathrm{ppm}$ $< 10 \mathrm{ppm}$ JP - Related Substances Passes Test Passes Test JP - Water $7.2 - 10.0 \%$ $\leq 0.10 \%$ $< 0.10 \%$ JP - Assay (anhydrous basis) $99.0 - 101.0 \%$ 100.3%	JP – Clarity and Color of Solution	Passes Test	Passes Test
$\begin{array}{llllllllllllllllllllllllllllllllllll$	JP – Sulfate (SO ₄)	≤ 0.028 %	< 0.028 %
JP - Related Substances Passes Test Passes Test JP - Water 7.2 - 10.0 % 8.1 % JP - Residue on Ignition $\leq 0.10 \%$ $< 0.10 \%$ JP - Assay (anhydrous basis) 99.0 - 101.0 % 100.3 %	JP – Ammonium (NH4)	≤ 0.02 %	< 0.02 %
JP - Water $7.2 - 10.0 \%$ 8.1% JP - Residue on Ignition $\leq 0.10 \%$ $< 0.10 \%$ JP - Assay (anhydrous basis) $99.0 - 101.0 \%$ 100.3%	JP – Iron (Fe)	≤ 10 ppm	< 10 ppm
JP – Residue on Ignition $\leq 0.10\%$ $< 0.10\%$ JP – Assay (anhydrous basis) $99.0 - 101.0\%$ 100.3%	JP – Related Substances	Passes Test	Passes Test
JP – Assay (anhydrous basis) 99.0 – 101.0 % 100.3 %	JP – Water	7.2 - 10.0 %	8.1 %
,,,	JP – Residue on Ignition	≤ 0.10 %	< 0.10 %
Endotoxin Concentration, IU/mg ,For Information Only < 0.003	JP – Assay (anhydrous basis)	99.0 - 101.0 %	100.3 %
	Endotoxin Concentration, IU/mg ,For Information Only		< 0.003

L-Histidine Monohydrochloride Multi-Compendial





Material No.: 4942-06 Batch No.: 24E2361036

Specification Result Test

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

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

