

Material No.: 4945-06  
Batch No.: 24E0961046  
Manufactured Date: 2023-02-01  
Expiration Date: 2026-01-31  
Release Date: 2024-05-24  
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 <sub>9</sub> H <sub>11</sub> NO <sub>2</sub> ) (dried basis)	98.5 – 101.5 %	99.9 %
USP – Identification	Passes Test	Passes Test
USP – Specific Rotation [A] <sup>25</sup> ^D (+)	-34.7 – -32.7 °	-34.1 °
USP – pH	5.4 – 6.0	5.7
USP – Loss on Drying at 105°C	≤ 0.3 %	< 0.1 %
USP – Residue on Ignition	≤ 0.4 %	< 0.1 %
USP – Chloride (Cl)	≤ 0.05 %	< 0.05 %
USP – Sulfate (SO <sub>4</sub> )	≤ 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 <sub>9</sub> H <sub>11</sub> NO <sub>2</sub> ) (dried basis)	98.5 – 101.0 %	100.0 %
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 [A] <sup>20</sup> ^D (+)	-35.5 – -33.0 °	-34.1 °
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 <sub>4</sub> )	≤ 300 ppm	< 300 ppm
EP/BP – Ammonium (NH <sub>4</sub> )	≤ 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 <sub>9</sub> H <sub>11</sub> NO <sub>2</sub> ) (dried basis)	98.5 – 101.0 %	99.0 %
JP – Identification	Passes Test	Passes Test
JP – Optical Rotation (+)	-35.5 – -33.0 °	-34.0 °
JP – pH	5.3 – 6.3	5.7

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Test	Specification	Result
JP - Clarity and Color of Solution	Passes Test	Passes Test
JP - Chloride (Cl)	≤ 0.021 %	< 0.021 %
JP - Sulfate (SO <sub>4</sub> )	≤ 0.028 %	< 0.028 %
JP - Ammonium (NH <sub>4</sub> )	≤ 0.02 %	< 0.02 %
JP - Related Substances	Passes Test	Passes Test
JP - Loss on Drying at 105°C	≤ 0.30 %	0.01 %
JP - Residue on Ignition	≤ 0.10 %	0.05 %
Endotoxin Concentration, IU/mg, For Information Only		< 0.003

GMP Manufactured Product  
Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

Only Class 2 Solvents (Methanol) are likely to be present. All are below Option 1 limits.

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.

Country of Origin: China

Packaging Site: Paris Mfg Ctr & DC

Manufacturer: P0005111

Manufacturer source batch: 23010675



Michelle Bales  
Sr. Manager, Quality Assurance