

Material No.: 2095-05
Batch No.: 22E1061086
Manufactured Date: 2019-12-19
Retest Date: 2024-12-17
Release Date: 2022-05-25
Revision No.: 0

Certificate of Analysis

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

Test	Specification	Result
USP – Assay ($C_5H_{11}NO_2$) (dried basis)	98.5 – 101.5 %	99.6 %
USP – Identification	Passes Test	Passes Test
USP – Specific Rotation $[A]^{25} \wedge D$ (+)	26.6 – 28.8 °	27.9 °
USP – pH	5.5 – 7.0	5.8
USP – Loss on Drying at 105°C	≤ 0.3 %	< 0.1 %
USP – Residue on Ignition	≤ 0.1 %	< 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 ($C_5H_{11}NO_2$) (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 $[A]^{20} \wedge D$ (+)	26.5 – 29.0 °	28.2 °
EP/BP–Ninhydrin–Positive Substances–Impurity B	≤ 0.4 %	< 0.4 %
EP/BP–Ninhydrin–Positive Substances–Each	≤ 0.2 %	< 0.2 %
EP/BP–Ninhydrin–Positive Substances–Total Impurities	≤ 1.0 %	< 1.0 %
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 – Assay ($C_5H_{11}NO_2$) (dried basis)	98.5 – 101.0 %	99.8 %
JP – Identification	Passes Test	Passes Test
JP – Optical Rotation (+)	26.5 – 29.0 °	28.2 °

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Test	Specification	Result
JP – pH	5.5 – 6.5	5.9
JP – Clarity and Color of Solution	Passes Test	Passes Test
JP – Chloride (Cl)	≤ 0.021 %	< 0.021 %
JP – Sulfate (SO ₄)	≤ 0.028 %	0.028 %
JP – Ammonium (NH ₄)	≤ 0.02 %	< 0.02 %
JP – Heavy Metals (as Pb)	≤ 20 ppm	< 20 ppm
JP – Arsenic (As)	≤ 2 ppm	< 2 ppm
JP – Related Substances	Passes Test	Passes Test
JP – Loss on Drying at 105°C	≤ 0.30 %	0.04 %
JP – Residue on Ignition	≤ 0.10 %	0.01 %
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.

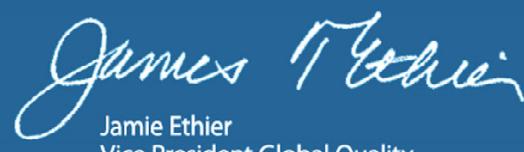
Elemental Impurities (USP (232), EP 5.20) – Information on elemental impurities for this product is available on the associated Product Regulatory Data Sheet and elemental impurity profile report.

Country of Origin: Japan

Packaging Site: Paris Mfg Ctr & DC

Manufacturer: P0062001

Manufacturer source batch: 190127


Jamie Ethier
Vice President Global Quality

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

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