



Material No.: 2078-06  
Batch No.: 0000179915  
Manufactured Date: 2016/04/22  
Retest Date: 2021/04/21

## Certificate of Analysis

Meets F.C.C. Requirements, Meets J.P. Chemical Specifications, Meets U.S.P Requirements,  
GMP Manufactured Product, Food GMP Manufactured Product

Test	Specification	Result
USP – Assay (C <sub>5</sub> H <sub>10</sub> N <sub>2</sub> O <sub>3</sub> ) (dried basis)	98.5 – 101.5 %	100.5
USP – Identification	Passes Test	PT
USP – Specific Rotation [A] <sup>20</sup> ^D (+)	6.3 – 7.3 Degree	6.6
USP – Loss on Drying at 105°C	<= 0.3 %	< 0.1
USP – Residue after Ignition	<= 0.3 %	< 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	Passes Test	PT
JP – Assay (C <sub>5</sub> H <sub>10</sub> N <sub>2</sub> O <sub>3</sub> ) (dried basis)	99.0 – 101.0 %	100.4
JP – Identification	Passes Test	PT
JP – Specific Rotation [A] <sup>20</sup> ^D (+)	6.3 – 7.3 Degree	6.6
JP – Loss on Drying at 105°C	<= 0.3 %	< 0.1
JP – Residue after Ignition	<= 0.1 %	< 0.1
JP – Chloride (Cl)	<= 0.021 %	< 0.021
JP – Sulfate (SO <sub>4</sub> )	<= 0.028 %	< 0.028
JP – Iron (Fe)	<= 10 ppm	< 10
JP – Heavy Metals (as Pb)	<= 10 ppm	< 10
JP – Chromatographic Purity	Passes Test	PT
JP – pH	4.5 – 6.0	5.2
JP – Clarity and Color of Solution	Passes Test	PT
JP – Ammonium	<= 0.1 %	0.1
FCC – Assay (as C <sub>5</sub> H <sub>10</sub> N <sub>2</sub> O <sub>3</sub> ) (dried basis)	98.0 – 101.5 %	100.5

Test	Specification	Result
FCC – Identification	Passes Test	PT
FCC – Lead (Pb)	<= 5 mg/kg	< 5
FCC – Loss on Drying	<= 0.3 %	< 0.1
FCC – Residue on Ignition	<= 0.3 %	< 0.1
FCC – Specific Rotation [A] <sup>20</sup> D (+)	6.3 – 7.3 Degree	6.6
FCC – Insoluble Foreign Matter	Passes Test	PT
Solubility of 3% Solution at 30°C	Passes Test	PT
Solubility of 3.5% Solution at 30°C	Passes Test	PT
Identification (by IR)	Passes Test	PT
Endotoxin Concentration (EU/mg)	<= 0.06	< 0.01
Endotoxin Concentration, IU/mg	Passes Test	PT

Bulk Food Chemical

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.

Country of Origin: JP  
 Packaging Site: Paris Mfg Ctr & DC  
 Manufacturer: P0062002  
 Manufacturer source batch: 160123

Phillipsburg, NJ 9001:2008, 14001:2004, FSSC 22000  
 Paris, KY 9001:2008  
 Mexico City, Mexico 9001:2008  
 Deventer, The Netherlands 9001:2008, 14001:2004, 13485:2003  
 Gliwice, Poland 9001:2008, 13485:2012  
 Selangor, Malaysia 9001:2008  
 Dehradun, India, 9001:2008, 14001:2004, 13485:2003  
 Mumbai, India, 9001:2008  
 Panoli, India 9001:2008

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