

Material No.: 2084-06  
Batch No.: 0000254254  
Manufactured Date: 2017/12/25  
Retest Date: 2022/12/24  
Release Date: 2020/03/23  
Revision No: 1

## 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>6</sub> H <sub>14</sub> N <sub>2</sub> O <sub>2</sub> · HCl) (dried basis)	98.5 – 101.5 %	99.4
USP – Identification	Passes Test	PT
USP – Specific Rotation [α] <sub>D</sub> <sup>25</sup> ^D (+)	20.4 – 21.4 Degree	21.1
USP – Loss on Drying at 105°C	<= 0.4 %	0.1
USP – Residue on Ignition	<= 0.1 %	< 0.1
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
USP – Chloride (Cl)	19.0 – 19.6 %	19.4
EP/BP – Assay (C <sub>6</sub> H <sub>14</sub> N <sub>2</sub> O <sub>2</sub> · HCl) (dried basis)	98.5 – 101.0 %	99.7
EP/BP – Identification A	Passes Test	PT
EP/BP – Identification B	Passes Test	PT
EP/BP – Identification E	Passes Test	PT
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – Specific Rotation [α] <sub>D</sub> <sup>20</sup> ^D (+)	21.0 – 22.5 Degree	21.7
EP/BP–Ninhydrin–Positive Substances–Each	<= 0.2 %	< 0.1
EP/BP–Ninhydrin–Positive Substances–Total Impurities	<= 1.0 %	< 0.1
EP/BP – Sulfate (SO <sub>4</sub> )	<= 300 ppm	< 300
EP/BP – Ammonium (NH <sub>4</sub> )	<= 0.02 %	< 0.02
EP/BP – Iron (Fe)	<= 30 ppm	< 30
EP/BP – Loss on Drying at 105°C	<= 0.5 %	0.1
EP/BP – Ash (sulfated)	<= 0.1 %	< 0.1

Test	Specification	Result
JP - Assay (C <sub>6</sub> H <sub>14</sub> N <sub>2</sub> O <sub>2</sub> · HCl) (dried basis)	98.5 - 101.0 %	99.7
JP - Identification A	Passes Test	PT
JP - Identification B	Passes Test	PT
JP - Optical Rotation (+)	19.0 - 21.5 Degree	21.1
JP - pH (1 in 10)	5.0 - 6.0	5.7
JP - Clarity and Color of Solution	Passes Test	PT
JP - Sulfate (SO <sub>4</sub> )	<= 0.028 %	< 0.028
JP - Ammonium (NH <sub>4</sub> )	<= 0.02 %	< 0.02
JP - Heavy Metals (as Pb)	<= 10 ppm	< 10
JP - Arsenic (As)	<= 2 ppm	< 2
JP - Related Substances	Passes Test	PT
JP - Loss on Drying at 105°C	<= 1.0 %	0.1
JP - Residue on Ignition	<= 0.10 %	0.05
Endotoxin Concentration, IU/mg, For Information Only		< 0.010

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 Conditions: Store in well-closed, light-resistant containers  
 Country of Origin: JP  
 Packaging Site: Paris Mfg Ctr & DC  
 Manufacturer: P0062001  
 Manufacturer source batch: 170345



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  
 Avantor Performance Materials, LLC  
 100 Matsonford Rd, Suite 200, Radnor, PA 19087. U.S.A. Phone: 610.386.1700