

Material No.: 2085-07  
Batch No.: 0000255085  
Manufactured Date: 2018/11/23  
Retest Date: 2023/11/22  
Release Date: 2020/04/02  
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>5</sub> H <sub>11</sub> NO <sub>2</sub> S) (dried basis)	98.5 – 101.5 %	99.7
USP – Identification	Passes Test	PT
USP – Specific Rotation [α] <sub>D</sub> <sup>25</sup> ^D (+)	22.4 – 24.7 Degree	23.4
USP – pH	5.6 – 6.1	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 – Methionine sulfoxide	<= 0.1 %	< 0.1
USP – Related Compounds – N-Acetyl-D,L-methionine	<= 0.2 %	< 0.2
USP – Related Compounds – Any unspecified impurity	<= 0.1 %	< 0.1
USP – Related Compounds – Total unspecified impurities	<= 0.30 %	< 0.30
EP/BP – Assay (C <sub>5</sub> H <sub>11</sub> NO <sub>2</sub> S) (dried basis)	99.0 – 101.0 %	99.6
EP/BP – Identification A	Passes Test	PT
EP/BP – Identification B	Passes Test	PT
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – pH	5.5 – 6.5	5.7

Test	Specification	Result
EP/BP – Specific Rotation $[\alpha]^{20}_D$ (+)	22.5 – 24.0 Degree	23.6
EP/BP – Related Substances: Unspecified Impurities, each	$\leq 0.10 \%$	$< 0.10$
EP/BP – Related Substances: Total Impurities	$\leq 0.3 \%$	$< 0.3$
EP/BP – Chloride (Cl)	$\leq 200$ ppm	$< 200$
EP/BP – Sulfate (SO <sub>4</sub> )	$\leq 300$ ppm	$< 300$
EP/BP – Ammonium (NH <sub>4</sub> )	$\leq 200$ ppm	$< 200$
EP/BP – Iron (Fe)	$\leq 10$ ppm	$< 10$
EP/BP – Loss on Drying at 105°C	$\leq 0.5 \%$	$< 0.1$
EP/BP – Ash (sulfated)	$\leq 0.1 \%$	$< 0.1$
JP – Assay (C <sub>5</sub> H <sub>11</sub> NO <sub>2</sub> S) (dried basis)	98.5 – 101.0 %	99.8
JP – Identification	Passes Test	PT
JP – Optical Rotation (+)	21.0 – 25.0 Degree	23.4
JP – pH	5.2 – 6.2	5.7
JP – Clarity and Color of Solution	Passes Test	PT
JP – Chloride (Cl)	$\leq 0.021 \%$	$< 0.021$
JP – Sulfate (SO <sub>4</sub> )	$\leq 0.028 \%$	$< 0.028$
JP – Ammonium (NH <sub>4</sub> )	$\leq 0.02 \%$	$< 0.02$
JP – Heavy Metals (as Pb)	$\leq 20$ ppm	$< 20$
JP – Arsenic (As)	$\leq 2$ ppm	$< 2$
JP – Related Substances	Passes Test	PT
JP – Loss on Drying at 105°C	$\leq 0.30 \%$	$< 0.01$
JP – Residue after Ignition	$\leq 0.10 \%$	$< 0.10$
Endotoxin Concentration, IU/mg, For Information Only		$< 0.010$
Metallic Impurities – Cobalt (Co), For Information Only	ppm	0.1

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: JP  
Packaging Site: Paris Mfg Ctr & DC  
Manufacturer: P3005001  
Manufacturer source batch: 199098

  
Jamie Ethier  
Vice President Global Quality