

Material No.: 2082-07  
Batch No.: 0000254891  
Manufactured Date: 2018/08/28  
Retest Date: 2023/08/27  
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>6</sub> H <sub>13</sub> NO <sub>2</sub> ) (dried basis)	98.5 – 101.5 %	100.5
USP – Identification	Passes Test	PT
USP – Specific Rotation [α] <sup>25</sup> ^D (+)	38.9 – 41.8 Degree	40.4
USP – pH	5.5 – 7.0	6.0
USP – Loss on Drying at 105°C	<= 0.3 %	< 0.1
USP – Residue on 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 – Individual Impurities	<= 0.5 %	< 0.5
USP – Related Compounds – Total Impurities	<= 2.0 %	< 2.0
EP/BP – Assay (C <sub>6</sub> H <sub>13</sub> NO <sub>2</sub> ) (dried basis)	98.5 – 101.0 %	100.8
EP/BP – Identification A	Passes Test	PT
EP/BP – Identification B	Passes Test	PT
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – Specific Rotation [α] <sup>20</sup> ^D (+)	40.0 – 43.0 Degree	41.6
EP/BP–Ninhydrin–Positive Substances–Impurity A	<= 0.3 %	0.1
EP/BP–Ninhydrin–Positive Substances–Impurity C	<= 0.3 %	< 0.1
EP/BP–Ninhydrin–Positive Substances–Each	<= 0.2 %	0.1
EP/BP–Ninhydrin–Positive Substances–Total Impurities	<= 1.0 %	0.2
EP/BP – Chloride (Cl)	<= 200 ppm	< 200
EP/BP – Sulfate (SO <sub>4</sub> )	<= 300 ppm	< 300
EP/BP – Ammonium (NH <sub>4</sub> )	<= 0.02 %	< 0.02

Test	Specification	Result
EP/BP – Iron (Fe)	<= 10 ppm	< 10
EP/BP – Loss on Drying	<= 0.5 %	< 0.1
EP/BP – Ash (sulfated)	<= 0.1 %	0.1
JP – Assay (C <sub>6</sub> H <sub>13</sub> NO <sub>2</sub> ) (dried basis)	98.5 – 101.0 %	100.1
JP – Identification	Passes Test	PT
JP – Optical Rotation (+)	39.5 – 41.5 Degree	40.9
JP – pH	5.5 – 6.5	6.0
JP – Clarity and Color of Solution	Passes Test	PT
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 – Heavy Metals (as Pb)	<= 20 ppm	< 20
JP – Arsenic (As)	<= 2 ppm	< 2
JP – Related Substances	Passes Test	PT
JP – Loss on Drying at 105°C	<= 0.30 %	0.02
JP – Residue on Ignition	<= 0.10 %	0.10
Endotoxin Concentration, IU/mg, For Information Only		< 0.003

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: P0062001  
 Manufacturer source batch: 182256



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