

L-Arginine  
Multi-Compendial



Material No.: 4932-07  
Batch No.: 0000267720  
Manufactured Date: 2020/02/28  
Expiration Date: 2023/02/27  
Release Date: 2020/09/18  
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>4</sub> O <sub>2</sub> ) (dried basis)	98.5 – 101.5 %	99.5
USP – Identification	Passes Test	PT
USP – Specific Rotation [α] <sup>25</sup> ^D (+)	26.3 – 27.7 Degree	26.9
USP – Loss on Drying at 105°C	<= 0.5 %	0.1
USP – Chloride (Cl)	<= 0.05 %	< 0.05
USP – Residue on Ignition	<= 0.3 %	< 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
EP/BP – Assay (C <sub>6</sub> H <sub>14</sub> N <sub>4</sub> O <sub>2</sub> ) (dried basis)	98.5 – 101.0 %	99.8
EP/BP – Identification A	Passes Test	PT
EP/BP – Identification C	Passes Test	PT
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – Specific Rotation [α] <sup>20</sup> ^D (+)	25.5 – 28.5 Degree	27.0
EP/BP–Ninhydrin–Positive Substances–Each	<= 0.2 %	< 0.2
EP/BP–Ninhydrin–Positive Substances–Total Impurities	<= 0.5 %	< 0.5
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
EP/BP – Iron (Fe)	<= 10 ppm	< 10
EP/BP – Loss on Drying	<= 0.5 %	0.1
EP/BP – Ash (sulfated)	<= 0.1 %	< 0.1

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

Test	Specification	Result
JP - Identification	Passes Test	PT
JP - Optical rotation, 20° C (+)	26.9 - 27.9 Degree	27.2
JP - pH (1:10)	10.5 - 12.0	11.2
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)	<= 10 ppm	< 10
JP - Iron (Fe)	<= 10 ppm	< 10
JP - Related Substances	Passes Test	PT
JP - Loss on Drying at 105°C	<= 0.3 %	0.1
JP - Residue after Ignition	<= 0.1 %	< 0.1
JP - Assay (C <sub>6</sub> H <sub>14</sub> N <sub>4</sub> O <sub>2</sub> )(dried basis)	98.5 - 101.0 %	99.5
Endotoxin Concentration, IU/mg, For Information Only		< 0.003

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: CN  
Packaging Site: Paris Mfg Ctr & DC  
Manufacturer: P0005111  
Manufacturer source batch: 20023163



Jamie Ethier  
Vice President Global Quality