L-Arginine, U.S.P.
Multi-Compendial

Material No.: 2066-06
Batch No.: 0000191567
Manufactured Date: 2017/07/31
Retest Date: 2022/07/30
Revision No: 1

Certificate of Analysis

Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications, 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 ($C_6H_{14}N_4O_2$) (dried basis)	98.5 - 101.5 %	100.1
USP - Identification	Passes Test	PT
USP - Specific Rotation [Å]^{25} ^D (+)	26.3 - 27.7 Degree	27.2
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_4)	<= 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
FCC - Assay ($C_6H_{14}N_4O_2$) (dried basis)	98.5 - 101.5 %	98.6
FCC - Identification	Passes Test	PT
FCC - Lead (Pb)	<= 5 mg/kg	< 5
FCC - Loss on Drying at 105°C	<= 1.0 %	0.4
FCC - Residue on Ignition	<= 0.2 %	0.1
FCC - Specific Rotation [Å]^{20}^D (+)	26.0 - 27.9 Degree	27.2
FCC - Insoluble Foreign Matter	Passes Test	PT
EP/BP - Assay ($C_6H_{14}N_4O_2$) (dried basis)	98.5 - 101.0 %	99.9
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 [Å]^{20}^D (+)	25.5 - 28.5 Degree	27.7

For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.573.2600
Avantor Performance Materials, LLC.
3477 Corporate Parkway. Center Valley, PA 18034. U.S.A. Phone: 610.573.2600 . Fax: 610.573.2610

Material No.: 2066-06
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Test	Specification	Result
EP/BP-Ninhydrin-Positive Substances-Each	<= 0.2 %	< 0.1
EP/BP-Ninhydrin-Positive Substances-Total Impurities	<= 0.5 %	< 0.1
EP/BP - Chloride (Cl)	<= 200 ppm	< 200
EP/BP - Sulfate (SO_4)	<= 300 ppm	< 300
EP/BP - Ammonium (NH_4)	<= 0.02 %	< 0.02
EP/BP - Iron (Fe)	<= 10 ppm	< 10
EP/BP - Loss on Drying	<= 0.5 %	0.5
EP/BP - Ash (sulfated)	<= 0.1 %	0.1
JP - Identification	Passes Test	PT
JP - Optical rotation, 20° C (+)	26.9 - 27.9 Degree	27.4
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_4)	<= 0.028 %	< 0.028
JP - Ammonium (NH_4)	<= 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 ($C_6H_{14}N_4O_2$)(dried basis)	98.5 - 101.0 %	98.6
Endotoxin Concentration, IU/mg, For Information Only		< 0.003

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.

Storage Conditions:	Preserve in well-closed containers.
Country of Origin:	JP
Packaging Site:	Paris Mfg Ctr & DC
Manufacturer:	P0062001
Manufacturer source batch:	172146

ISO
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

James Ethier
Jamie Ethier
Vice President Global Quality

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