

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



Material No.: 2089-06
Batch No.: 0000165511
Manufactured Date: 2015/03/05
Retest Date: 2020/03/03

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 ₄ H ₈ NO ₃) (dried basis)	98.5 – 101.5 %	99.8
USP – Identification	Passes Test	PT
USP – Specific Rotation [A] ²⁵ ^D	-29.1 – -26.7 Degree	-28.1
USP – pH	5.0 – 6.5	5.6
USP – Loss on Drying at 105°C	<= 0.2 %	0.1
USP – Residue on Ignition	<= 0.4 %	0.1
USP – Chloride (Cl)	<= 0.05 %	< 0.05
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
USP – Heavy Metals (as Pb)	<= 0.0015 %	< 0.0015
FCC – Assay (C ₄ H ₈ NO ₃) (dried basis)	98.5 – 101.5 %	99.9
FCC – Identification	Passes Test	PT
FCC – Lead (Pb)	<= 5 mg/kg	< 5
FCC – Loss on Drying	<= 0.2 %	< 0.1
FCC – Residue on Ignition	<= 0.1 %	0.1
FCC – Specific Rotation [A] ²⁰ ^D	-29.0 – -26.5 Degree	-28.5
EP/BP – Assay (C ₄ H ₈ NO ₃) (dried basis)	99.0 – 101.0 %	99.8
EP/BP – Identification A	Passes Test	PT
EP/BP – Identification B	Passes Test	PT

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

Test	Specification	Result
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – pH	5.0 – 6.5	5.6
EP/BP – Specific Rotation $[\alpha]^{20\wedge D}$	-29.0 – -27.6 Degree	-28.5
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 – Heavy Metals (as Pb)	<= 10 ppm	< 10
EP/BP – Loss on Drying	<= 0.5 %	< 0.1
EP/BP – Ash (sulfated)	<= 0.1 %	0.1
JP – Assay (C ₄ H ₈ NO ₃) (dried basis)	98.5 – 101.0 %	99.0
JP – Identification	Passes Test	PT
JP – Optical Rotation	-29.0 – -26.0 Degree	-28.5
JP – pH	5.2 – 6.2	5.7
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)	<= 20 ppm	< 20
JP – Arsenic (As)	<= 2 ppm	< 2
JP – Related Substances	Passes Test	PT
JP – Loss on Drying at 105°C	<= 0.20 %	0.10
JP – Residue on Ignition	<= 0.10 %	0.10
Endotoxin Concentration, IU/mg, For Information Only		< 0.001

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.

Metallic Residues: No metal catalysts or metal reagents, as defined by

EMA Guideline EMEA/CHMP/SWP/4446/2000 , are used in the production of this material.

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Storage Conditions: Store in well-closed, light-resistant containers
Country of Origin: JP
Packaging Site: Paris Mfg Ctr & DC
Manufacturer: P0062001
Manufacturer source batch: 151446

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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