

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



Material No.: 2085-05
Batch No.: 0000171632
Manufactured Date: 2015/06/23
Retest Date: 2020/06/21

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 ₅ H ₁₁ NO ₂ S) (dried basis)	98.5 – 101.5 %	100.0
USP – Identification	Passes Test	PT
USP – Specific Rotation [A] ²⁵ ^D (+)	22.4 – 24.7 Degree	23.3
USP – pH	5.6 – 6.1	6.1
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 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 ₅ H ₁₁ NO ₂ S) (dried basis)	98.5 – 101.5 %	100.3
FCC – Identification	Passes Test	PT
FCC – Lead (Pb)	<= 5 mg/kg	< 5
FCC – Loss on Drying at 105°C	<= 0.5 %	< 0.1
FCC – Residue on Ignition	<= 0.1 %	< 0.1
FCC – Specific Rotation [A] ²⁰ ^D (+)	21.0 – 25.0 Degree	23.6
FCC – Insoluble Foreign Matter	Passes Test	PT
EP/BP – Assay (C ₅ H ₁₁ NO ₂ S) (dried basis)	99.0 – 101.0 %	100.1
EP/BP – Identification A	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 – Identification B	Passes Test	PT
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – pH	5.5 – 6.5	6.0
EP/BP – Specific Rotation $[\alpha]_D^{20}$ (+)	22.5 – 24.0 Degree	23.5
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)	≤ 200 ppm	< 200
EP/BP – Sulfate (SO ₄)	≤ 300 ppm	< 300
EP/BP – Ammonium (NH ₄)	≤ 200 ppm	< 200
EP/BP – Heavy Metals (as Pb)	≤ 10 ppm	< 10
EP/BP – Iron (Fe)	≤ 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 ₅ H ₁₁ NO ₂ S) (dried basis)	98.5 – 101.0 %	100.0
JP – Identification	Passes Test	PT
JP – Optical Rotation (+)	21.0 – 25.0 Degree	23.5
JP – pH	5.2 – 6.2	6.0
JP – Clarity and Color of Solution	Passes Test	PT
JP – Chloride (Cl)	$\leq 0.021\%$	< 0.021
JP – Sulfate (SO ₄)	$\leq 0.028\%$	< 0.028
JP – Ammonium (NH ₄)	$\leq 0.02\%$	< 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	$\leq 0.30\%$	0.01
JP – Residue after Ignition	$\leq 0.10\%$	0.03
Endotoxin Concentration, IU/mg, For Information Only		< 0.003

Bulk Food Chemical

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.

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.

Material No.: 2085-05
Batch No.: 0000171632

Country of Origin: JP
Packaging Site: Paris Mfg Ctr & DC
Manufacturer: P3005001
Manufacturer source batch: 159743

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


Jamie Ethier
Vice President Global Quality

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