

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



Material No.: 2095-05
Batch No.: 0000108952
Manufactured Date: 2013/06/24
Retest Date: 2018/06/23

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) (dried basis)	98.5 – 101.5 %	99.8
USP – Identification	Passes Test	PT
USP – Specific Rotation [A] ²⁵ ^D (+)	26.6 – 28.8 Degree	27.1
USP – pH	5.5 – 7.0	6.0
USP – Loss on Drying at 105°C	<= 0.3 %	< 0.1
USP – Residue on Ignition	<= 0.1 %	< 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) (dried basis)	98.5 – 101.5 %	99.3
FCC – Identification	Passes Test	PT
FCC – Lead (Pb)	<= 5 mg/kg	< 5
FCC – Loss on Drying	<= 0.3 %	< 0.1
FCC – Residue on Ignition	<= 0.1 %	< 0.1
FCC – Specific Rotation [A] ²⁰ ^D (+)	26.7 – 29.0 Degree	27.1
FCC – Insoluble Foreign Matter	Passes Test	PT
EP/BP – Assay (C ₅ H ₁₁ NO ₂) (dried basis)	98.5 – 101.0 %	99.3
EP/BP – Identification A	Passes Test	PT

Test	Specification	Result
EP/BP – Identification B	Passes Test	PT
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – Specific Rotation $[\alpha]^{20}_D (+)$	26.5 – 29.0 Degree	27.1
EP/BP–Ninhydrin–Positive Substances–Impurity B	<= 0.4 %	< 0.1
EP/BP–Ninhydrin–Positive Substances–Each	<= 0.2 %	< 0.1
EP/BP–Ninhydrin–Positive Substances–Total Impurities	<= 1.0 %	< 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 – Heavy Metals (as Pb)	<= 10 ppm	< 10
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 ₅ H ₁₁ NO ₂) (dried basis)	98.5 – 101.0 %	99.3
JP – Identification	Passes Test	PT
JP – Optical Rotation (+)	26.5 – 29.0 Degree	27.1
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 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	<= 0.30 %	< 0.01
JP – Residue on Ignition	<= 0.10 %	< 0.01
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.

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Country of Origin: JP
Packaging Site: Paris Mfg Ctr & DC
Manufacturer: P0062001
Manufacturer source batch: 131522

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, 17025:2005
Selangor, Malaysia 9001:2008
Dehradun, India, 9001:2008, 14001:2004, 13485:2003
Mumbai, India, 9001:2008, 17025:2005
Panoli, India 9001:2008



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