

L-Alanine
Multi-Compendial



Material No.: 6253-06
Batch No.: 0000150788
Manufactured Date: 2014/05/08
Retest Date: 2019/05/07

Certificate of Analysis

Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications, Meets U.S.P Requirements,
GMP Manufactured Product

Test	Specification	Result
USP – Identification	Passes Test	PT
USP – Assay (dried basis)	98.5 – 101.5 %	98.8
USP – Residue on Ignition	<= 0.15 %	0.13
USP – Chloride (Cl)	<= 0.05 %	< 0.05
USP – Sulfate (SO ₄)	<= 0.03 %	< 0.03
USP – Iron (Fe)	<= 30 ppm	< 30
USP – Heavy Metals (as Pb)	<= 15 ppm	< 15
USP – Related Compounds – Individual Impurities	<= 0.5 %	< 0.5
USP – Related Compounds – Total Impurities	<= 2.0 %	< 2.0
USP – Specific Rotation [α] _D ²⁵ ^D (+)	13.7 – 15.1 Degree	14.8
USP – pH	5.5 – 7.0	6.3
USP – Loss on Drying	<= 0.2 %	<0.1
EP – Identification A	Passes Test	PT
EP – Identification B	Passes Test	PT
EP – Appearance of Solution	Passes Test	PT
EP – Specific optical rotation (+)	13.5 – 15.5 Degree	14.8
EP/BP – Ninhydrin Positive Substances – Each Impurity	<= 0.10	< 0.05
EP/BP–Ninhydrin–Positive Substances–Total Impurities	<= 0.5 %	< 0.5
EP – Chloride (Cl)	<= 200 ppm	< 200
EP – Sulfate (SO ₄)	<= 300 ppm	< 300
EP/BP – Ammonium (NH ₄)	<= 0.02 %	< 0.02
EP – Iron (Fe)	<= 10 ppm	< 10

Test	Specification	Result
EP - Heavy Metals (as Pb)	<= 10 ppm	< 10
EP - Loss on Drying at 105°C	<= 0.5 %	<0.1
EP - Sulfated Ash	<= 0.1 %	0.1
EP - Assay (dried basis)	98.5 - 101.0 %	100.0

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.

Country of Origin: JP
Packaging Site: Paris Mfg Ctr & DC
Manufacturer: P0062001
Manufacturer source batch: 141705



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

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