

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



Material No.: 2092-06
Batch No.: 0000171254
Manufactured Date: 2015/08/27
Retest Date: 2020/08/25

Certificate of Analysis

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 ₁₁ H ₁₂ N ₂ O ₂) (dried basis)	98.5 – 101.5 %	99.6
USP – Identification	Passes Test	PT
USP – Specific Rotation [A] ²⁵ ^D	-32.8 – -29.4 Degree	-31.9
USP – pH	5.5 – 7.0	5.8
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 – Organic Impurities – Total Impurities 1	<= 0.01 %	< 0.01
USP – Organic Impurities – Total Impurities 2	<= 0.03 %	< 0.03
USP – Organic Impurities – Tryptophan Related Compound A	<= 10 ppm	< 5
FCC – Assay (C ₁₁ H ₁₂ N ₂ O 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 at 105°C	<= 0.3 %	< 0.1
FCC – Residue on Ignition	<= 0.1 %	< 0.1
FCC – Specific Rotation [A] ²⁵ ^D	-32.7 – -29.7 Degree	-32.0
JP – Assay (C ₁₁ H ₁₂ N ₂ O ₂) (dried basis)	98.5 – 101.0 %	99.5
JP – Identification	Passes Test	PT
JP – Specific Rotation [A] ²⁰ ^D	-33.0 – -30.0 Degree	-32.0

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
JP – pH	5.4 – 6.4	5.8
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		< 0.001
EP – Identification A	Passes Test	PT
EP – Identification B	Passes Test	PT
EP – Appearance of Solution	Passes Test	PT
EP – Specific Optical Rotation [A] ²⁰ _D	-33.0 – -30.0 Degree	-31.8
EP/BP–Ninhydrin–Positive Substances–Each	<= 0.2 %	< 0.1
EP/BP–Ninhydrin–Positive Substances–Total Impurities	<= 0.5 %	< 0.1
EP – 1,1'Ethylidenebistryptophan	<= 10 ppm	< 10
EP – Sum of the Areas less than Tryptophan®	<= 100 ppm	< 100
EP – Sum of the Areas greater than Tryptophan®	<= 300 ppm	< 300
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)	<= 20 ppm	< 20
EP – Loss on Drying at 105°C	<= 0.5 %	< 0.1
EP – Sulfated Ash	<= 0.1 %	< 0.1
EP – Assay (C ₁₁ H ₁₂ N ₂ O ₂) (dried basis)	98.5 – 101.0 %	99.5

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.

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.

Material No.: 2092-06
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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: 151334

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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