

Material No.: 2092-06
Batch No.: 0000259097
Manufactured Date: 2018/11/15
Retest Date: 2023/11/14
Release Date: 2020/05/21
Revision No: 1

Certificate of Analysis

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

Test	Specification	Result
USP – Assay (C ₁₁ H ₁₂ N ₂ O ₂) (dried basis)	98.5 – 101.5 %	100.1
USP – Identification	Passes Test	PT
USP – Specific Rotation [α] ²⁵ ^D	-32.8 – -29.4 Degree	-31.3
USP – pH	5.5 – 7.0	5.9
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
JP – Assay (C ₁₁ H ₁₂ N ₂ O ₂) (dried basis)	98.5 – 101.0 %	99.6
JP – Identification	Passes Test	PT
JP – Specific Rotation [α] ²⁰ ^D	-33.0 – -30.0 Degree	-31.9
JP – pH	5.4 – 6.4	5.9
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

Test	Specification	Result
JP - Related Substances	Passes Test	PT
JP - Loss on Drying at 105°C	<= 0.30 %	< 0.10
JP - Residue on Ignition	<= 0.10 %	< 0.10
Endotoxin Concentration, IU/mg, For Information Only		< 0.010
EP - Identification A	Passes Test	PT
EP - Identification B	Passes Test	PT
EP - Appearance of Solution	Passes Test	PT
EP - Specific Optical Rotation [α] _D ²⁰	-33.0 - -30.0 Degree	-31.9
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 %	100.3

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.

Storage Conditions: Store in well-closed, light-resistant containers

Country of Origin: JP

Packaging Site: Paris Mfg Ctr & DC

Manufacturer: P0062001

Manufacturer source batch: 181731



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For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.386.1700
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