



Material No.: 2086-07
Batch No.: 0000182226
Manufactured Date: 2016/12/21
Retest Date: 2021/12/20

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 ₉ H ₁₁ NO ₂) (dried basis)	98.5 – 101.5 %	100.2
USP – Identification	Passes Test	PT
USP – Specific Rotation [α] ²⁵ _D (+)	-34.7 – -32.7 Degree	-33.8
USP – pH	5.4 – 6.0	5.6
USP – Loss on Drying at 105°C	<= 0.3 %	< 0.2
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
FCC – Assay (C ₉ H ₁₁ NO ₂) (dried basis)	98.5 – 101.5 %	99.9
FCC – Identification	Passes Test	PT
FCC – Lead (Pb)	<= 5 mg/kg	< 5
FCC – Loss on Drying	<= 0.2 %	< 0.1
FCC – Residue on Ignition	<= 0.1 %	< 0.1
FCC – Specific Rotation [α] ²⁰ _D (+)	-35.2 – -33.2 Degree	-34.3
EP/BP – Assay (C ₉ H ₁₁ NO ₂) (dried basis)	98.5 – 101.0 %	100.8
EP/BP – Identification A	Passes Test	PT
EP/BP – Identification B	Passes Test	PT
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – Specific Rotation [α] ²⁰ _D (+)	-35.5 – -33.0 Degree	-34.4

Test	Specification	Result
EP/BP-Ninhydrin-Positive Substances-Each	<= 0.2 %	< 0.1
EP/BP-Ninhydrin-Positive Substances-Total Impurities	<= 0.5 %	< 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 - 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 ₉ H ₁₁ NO ₂) (dried basis)	98.5 - 101.0 %	98.5
JP - Identification	Passes Test	PT
JP - Optical Rotation (+)	-35.5 - -33.0 Degree	-34.4
JP - pH	5.3 - 6.3	5.6
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 %	0.03
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.

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: 161325

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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 Vice President Global Quality

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