



Material No.: 2081-06
Batch No.: 0000172219
Manufactured Date: 2017/02/24
Retest Date: 2022/02/23

Certificate of Analysis

Meets B.P. Chemical Specifications, Meets E.P. Chemical Specifications, Meets F.C.C. Requirements, Meets J.P. Chemical Specifications,
GMP Manufactured Product, Food GMP Manufactured Product

Test	Specification	Result
FCC - Assay (C ₆ H ₉ N ₃ O ₂ · HCl) (dried basis)	98.5 - 101.5 %	99.0
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 after Ignition	<= 0.1 %	<0.01
FCC - Specific Rotation [A] ²⁰ _D (+)	8.5 - 10.5 Degree	9.2
EP/BP - Assay (C ₆ H ₉ N ₃ O ₂ · HCl) (dried basis)	98.5 - 101.0 %	99.8
EP/BP - Identification A	Passes Test	PT
EP/BP - Identification B	Passes Test	PT
EP/BP - Identification C	Passes Test	PT
EP/BP - Identification F	Passes Test	PT
EP/BP - Appearance of Solution	Passes Test	PT
EP/BP - pH	3.0 - 5.0	4.0
EP/BP - Specific Rotation [A] ²⁰ _D (+)	9.2 - 10.6 Degree	10.1
EP/BP-Ninhydrin-Positive Substances-Each	<= 0.2 %	< 0.1
EP/BP-Ninhydrin-Positive Substances-Total Impurities	<= 0.5 %	< 0.1
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 at 150°C	7.0 - 10.0 %	8.6
EP/BP - Ash (sulfated)	<= 0.1 %	< 0.1
JP - Identification	Passes Test	PT
JP - Optical Rotation (+)	9.2 - 10.6	10.1

Test	Specification	Result
JP - pH	3.5 - 4.5	4.0
JP - Clarity and Color of Solution	Passes Test	PT
JP - Sulfate (SO ₄)	<= 0.028 %	< 0.028
JP - Ammonium (NH ₄)	<= 0.02 %	< 0.02
JP - Heavy Metals (as Pb)	<= 10 ppm	< 10
JP - Iron (Fe)	<= 10 ppm	< 10
JP - Related Substances	Passes Test	PT
JP - Water	7.2 - 10.0 %	8.7
JP - Residue on Ignition	<= 0.1 %	0.0
JP - Assay (anhydrous basis)	99.0 - 101.0 %	99.0
Endotoxin Concentration, IU/mg ,For Information Only		< 0.01

Bulk Food Chemical

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.

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 airtight container.
Country of Origin: JP
Packaging Site: Paris Mfg Ctr & DC
Manufacturer: P0062001
Manufacturer source batch: 160461



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



Jamie Ethier
Vice President Global Quality

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