



Material No.: 2071-05
Batch No.: 0000195127
Manufactured Date: 2016/11/01
Retest Date: 2021/10/31
Revision No: 1

Certificate of Analysis

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

Test	Specification	Result
USP – Assay (C ₃ H ₇ NO ₂ S · HCl) (dried basis)	98.5 – 101.5 %	99.8
USP – Identification	Passes Test	PT
USP – Specific Rotation [α] ²⁵ ^D (+)	5.7 – 6.8 Degree	6.2
USP – Loss on Drying	8.0 – 12.0 %	9.1
USP – Residue on Ignition	<= 0.1 %	< 0.1
USP – Sulfate (SO ₄)	<= 0.03 %	< 0.03
USP – Iron (Fe)	<= 0.003 %	< 0.003
USP – Heavy Metals (as Pb)	<= 0.0015 %	< 0.0015
USP – Related Compounds – Individual Impurities	<= 0.5 %	< 0.5
USP – Related Compounds – Total Impurities	<= 2.0 %	< 2.0
FCC – Assay (C ₃ H ₇ NO ₂ S · HCl) (dried basis)	98.0 – 101.5 %	100.8
FCC – Identification	Passes Test	PT
FCC – Lead (Pb)	<= 5 mg/kg	< 5
FCC – Loss on Drying	8.0 – 12.0 %	9.1
FCC – Residue on Ignition	<= 0.1 %	< 0.1
FCC – Specific Rotation [α] ²⁰ ^D (+)	5.0 – 8.0 Degree	6.7
EP/BP – Assay (C ₃ H ₇ NO ₂ S · HCl) (dried basis)	98.5 – 101.0 %	99.3
EP/BP – Identification A	Passes Test	PT
EP/BP – Identification B	Passes Test	PT
EP/BP – Identification E	Passes Test	PT
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – Specific Rotation [α] ²⁰ ^D (+)	5.5 – 7.0 Degree	6.5
EP/BP – Ninhydrin-Positive Substances – Impurity A	<= 0.5 %	< 0.1

Test	Specification	Result
EP/BP-Ninhydrin-Positive Substances-Each	<= 0.2 %	< 0.1
EP/BP-Ninhydrin-Positive Substances-Total Impurities	<= 1.0 %	< 0.1
EP/BP - Sulfate (SO ₄)	<= 300 ppm	< 300
EP/BP - Ammonium (NH ₄)	<= 0.02 %	< 0.02
EP/BP - Iron (Fe)	<= 20 ppm	< 20
EP/BP - Heavy Metals (as Pb)	<= 10 ppm	< 10
EP/BP - Loss on Drying	8.0 - 12.0 %	9.1
EP/BP - Ash (sulfated)	<= 0.1 %	< 0.1
Endotoxin Concentration, IU/mg, For Information Only		< 0.005

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.

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: P0063001
 Manufacturer source batch: 179083

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

For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.573.2600
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