



Material No.: 2083-07
Batch No.: 0000181845
Manufactured Date: 2017/02/28
Retest Date: 2022/02/27

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 ₆ H ₁₃ NO ₂) (dried basis)	98.5 – 101.5 %	99.9
USP – Identification	Passes Test	PT
USP – Specific Rotation [α] ²⁵ ^D (+)	14.9 – 17.3 Degree	15.5
USP – pH	5.5 – 7.0	5.9
USP – Loss on Drying at 105°C	<= 0.2 %	0.1
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 %	< 0.2
FCC – Assay (C ₆ H ₁₃ 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 at 105°C	<= 0.2 %	0.1
FCC – Residue on Ignition	<= 0.1 %	< 0.1
FCC – Specific Rotation [α] ²⁵ ^D (+)	14.8 – 16.8 Degree	15.2
FCC – Insoluble Foreign Matter	Passes Test	PT
EP/BP – Assay (C ₆ H ₁₃ 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

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
EP/BP – Specific Rotation $[\alpha]_D^{20}$ (+)	14.5 – 16.5 Degree	15.2
EP/BP–Ninhydrin–Positive Substances–Impurity A	<= 0.8 %	< 0.8
EP/BP–Ninhydrin–Positive Substances–Each	<= 0.2 %	< 0.2
EP/BP–Ninhydrin–Positive Substances–Total Impurities	<= 1.0 %	< 1.0
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 at 105°C	<= 0.5 %	0.1
EP/BP – Ash (sulfated)	<= 0.1 %	< 0.1
JP – Assay (C ₆ H ₁₃ NO ₂) (dried basis)	98.5 – 101.0 %	100.6
JP – Identification	Passes Test	PT
JP – Optical Rotation (+)	14.5 – 16.0 Degree	15.2
JP – pH	5.5 – 6.5	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
JP – Related Substances	Passes Test	PT
JP – Loss on Drying at 105°C	<= 0.30 %	0.10
JP – Residue after Ignition	<= 0.10 %	< 0.10
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.

Country of Origin: JP
 Packaging Site: Paris Mfg Ctr & DC
 Manufacturer: P0062001
 Manufacturer source batch: 171817



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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