

Material No.: 2083-07
Batch No.: 0000249203
Manufactured Date: 2018/09/05
Retest Date: 2023/09/04
Release Date: 2020/02/24
Revision No: 1

Certificate of Analysis

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

Test	Specification	Result
USP – Assay (C ₆ H ₁₃ NO ₂) (dried basis)	98.5 – 101.5 %	101.2
USP – Identification	Passes Test	PT
USP – Specific Rotation [α] ²⁵ ^D (+)	14.9 – 17.3 Degree	15.4
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 %	< 2.0
EP/BP – Assay (C ₆ H ₁₃ NO ₂) (dried basis)	98.5 – 101.0 %	100.7
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 (+)	14.5 – 16.5 Degree	15.8
EP/BP–Ninhydrin–Positive Substances–Impurity A	<= 0.8 %	< 0.1
EP/BP–Ninhydrin–Positive Substances–Each	<= 0.2 %	0.1
EP/BP–Ninhydrin–Positive Substances–Total Impurities	<= 1.0 %	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

Test	Specification	Result
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 %	99.9
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 %	0.01
JP – Residue after Ignition	<= 0.10 %	0.02
Endotoxin Concentration, IU/mg, For Information Only		< 0.010

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: 182008



Jamie Ethier
 Vice President Global Quality

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