

Material No.: 2089-06
Batch No.: 0000252860
Manufactured Date: 2017/10/02
Retest Date: 2022/10/01
Release Date: 2020/03/05
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 ₄ H ₈ NO ₃) (dried basis)	98.5 – 101.5 %	99.3
USP – Identification	Passes Test	PT
USP – Specific Rotation [Å] ²⁵ ^D	-29.1 – -26.7 Degree	-28.3
USP – pH	5.0 – 6.5	5.6
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 ₄ H ₈ NO ₃) (dried basis)	99.0 – 101.0 %	100.4
EP/BP – Identification A	Passes Test	PT
EP/BP – Identification B	Passes Test	PT
EP/BP – Appearance of Solution	Passes Test	PT
EP/BP – pH	5.0 – 6.5	5.7
EP/BP – Specific Rotation [Å] ²⁰ ^D	-29.0 – -27.6 Degree	-28.5
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

Test	Specification	Result
EP/BP – Loss on Drying	<= 0.5 %	0.1
EP/BP – Ash (sulfated)	<= 0.1 %	0.1
JP – Assay (C ₄ H ₈ NO ₃) (dried basis)	98.5 – 101.0 %	99.9
JP – Identification	Passes Test	PT
JP – Optical Rotation	-29.0 – -26.0 Degree	-28.3
JP – pH	5.2 – 6.2	5.5
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	<= 0.20 %	0.01
JP – Residue on Ignition	<= 0.10 %	0.09
Endotoxin Concentration, IU/mg, For Information Only		< 0.001

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 well-closed, light-resistant containers

Country of Origin: JP

Packaging Site: Paris Mfg Ctr & DC

Manufacturer: P0062001

Manufacturer source batch: 171533



Jamie Ethier
Vice President Global Quality