

Material No.: 4074-QM
Batch No.: 22L1961051
Manufactured Date: 2021-12-20
Retest Date: 2026-12-19
Release Date: 2023-01-06
Revision No.: 0

Certificate of Analysis

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

Test	Specification	Result
NF – Identification	Passes Test	Passes Test
NF – Appearance of Solution	Passes Test	Passes Test
NF – Color Value	≤ 45	4
NF – Conductivity	≤ 35 µS/cm	1 µS/cm
NF – Optical Rotation (+)	66.3 – 67.0 °	66.3 °
NF – Reducing Sugars	Passes Test	Passes Test
NF – Sulfite (SO ₂)	≤ 10 ppm	< 10 ppm
NF – Loss on Drying at 105 °C	≤ 0.1 %	0.1 %
EP/BP – Identification A (EP/BP)	Passes Test	Passes Test
EP/BP – Appearance of Solution	Passes Test	Passes Test
EP/BP – Conductivity, uS cm ⁻¹	≤ 35	1
EP/BP – Optical Rotation (+)	66.3 – 67.0 °	66.3 °
EP/BP – Colour Value	≤ 45	4
EP/BP – Reducing Sugars	Passes Test	Passes Test
EP/BP – Sulfite (SO ₂)	≤ 10 ppm	< 10 ppm
EP/BP – Loss on Drying at 105°C	≤ 0.1 %	< 0.1 %
JP – Identification	Passes Test	Passes Test
JP – Optical Rotation (+)	66.3 – 67.0 °	66.3 °
JP – Clarity of Solution	Passes Test	Passes Test
JP – Color Value	≤ 45	4
JP – Sulfite (SO ₂)	≤ 10 ppm	< 10 ppm
JP – Reducing Sugars	Passes Test	Passes Test
JP – Conductivity, uS cm ⁻¹	≤ 35	1
JP – Loss on Drying at 105°C	≤ 0.1 %	< 0.1 %
Endotoxin Concentration (EU/g)	≤ 250	< 25

GMP Manufactured Product

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.

Store in a tightly closed container.

Country of Origin: USA

Packaging Site: Paris Mfg Ctr & DC

Manufacturing Site: Paris, France
Manufacturer: P0072001

Manufacturer: 10072001
Manufacturer source batch: 71511

James Ethier
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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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