

Material No.: 9526-26
Batch No.: 0000274970
Manufactured Date: 2020/11/24
Retest Date: 2025/11/23
Release Date: 2021/01/15
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 – Identification	Passes Test	PT
USP – Congealing Temperature	$\geq 15.6^{\circ}\text{C}$	16.6
USP – Nonvolatile Residue (USP), mg/20 mL	≤ 1.0	< 0.1
USP – Chloride (Cl)	Passes Test	PT
USP – Sulfate (SO_4)	Passes Test	PT
USP – Readily Oxidizable Substances	Passes Test	PT
USP – Assay (CH_3COOH)	99.5 – 100.5 %	100.0
EP/BP – Identification A	Passes Test	PT
EP/BP – Identification B	Passes Test	PT
EP/BP – Appearance	Passes Test	PT
EP/BP – Freezing Point	$\geq 14.8^{\circ}\text{C}$	16.6
EP/BP – Iron (Fe)	≤ 5 ppm	< 5
EP/BP – Chloride (Cl)	≤ 25 ppm	< 25
EP/BP – Sulfate (SO_4)	≤ 50 ppm	< 50
EP/BP – Reducing Substances	Passes Test	PT
EP/BP – Residue on Evaporation	≤ 0.01 %	< 0.01
EP/BP – Assay (CH_3COOH)	99.0 – 100.5 %	100.2
JP – Assay (CH_3COOH)	99.0 – 101.0 %	100.2
JP – Identification	Passes Test	PT
JP – Congealing Point	$\geq 14.5^{\circ}\text{C}$	16.6
JP – Nonvolatile Residue, mg/10 mL	≤ 1.0	0.1
JP – Chloride (Cl)	Passes Test	PT
JP – Sulfate (SO_4)	Passes Test	PT

Test	Specification	Result
JP – Heavy Metals (as Pb)	<= 10 ppm	< 10
JP – Reducing Substances	Passes Test	PT

Bulk Pharmaceutical Chemical

CAUTION: For Manufacturing, processing or repackaging

Residual Solvents: No Class 1, 2 or 3 residual solvents are used in or produced by the production process.

Preserve in tight containers, and store at room temperature

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: US
Packaging Site: Phillipsburg Mfg Ctr & DC
Manufacturer: P0018002
Manufacturer source batch: 90132965


Jamie Ethier
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