Acetic Acid, Glacial, U.S.P. Multi-Compendial



Material No.: 9526-03

Revision No.: 0

## **Product Specification**

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

Test	Specification	
USP - Identification	Passes Test	
USP - Congealing Temperature	≥ 15,6 °C	
USP - Nonvolatile Residue (USP), mg/20 mL	≤ 1,0	
USP - Chloride (CI)	Passes Test	
USP - Sulfate (SO <sub>4</sub> )	Passes Test	
USP - Readily Oxidizable Substances	Passes Test	
USP - Assay (CH₃COOH)	99,5 - 100,5 %	
EP/BP - Identification A	Passes Test	
EP/BP - Identification B	Passes Test	
EP/BP - Appearance	Passes Test	
EP/BP - Freezing Point	≥ 14,8 °C	
EP/BP - Iron (Fe)	≤ 5 ppm	
EP/BP - Chloride (Cl)	≤ 25 ppm	
EP/BP - Sulfate (SO <sub>4</sub> )	≤ 50 ppm	
EP/BP - Reducing Substances	Passes Test	
EP/BP - Residue on Evaporation	≤ 0,01 %	
EP/BP - Assay (CH₃COOH)	99,0 - 100,5 %	
JP - Assay (CH₃COOH)	99,0 - 101,0 %	
JP - Identification	Passes Test	
JP - Congealing Point	≥ 14,5 °C	
JP - Nonvolatile Residue, mg/10 mL	≤ 1,0	
JP - Chloride (CI)	Passes Test	
JP - Sulfate (SO <sub>4</sub> )	Passes Test	
JP - Heavy Metals (as Pb)	≤ 10 ppm	
JP - Reducing Substances	Passes Test	

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Test Specification

GMP Manufactured Product 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.

Storage Condition: IMPORTANT: Material will freeze if stored below 17  $^{\circ}$ C (63 $^{\circ}$ F).

Packaging Site: Phillipsburg Mfg Ctr & DC

