



# Specification

1.01544.0001 L-Arginine monohydrochloride EMPROVE® EXPERT Ph Eur, BP, ChP, JP, USP

Specification		
Assay (perchloric acid titration, calculated on dried substance)	98.5 - 101.0	%
Identity (IR-spectrum)	passes test	
Identity (wet chemistry)	passes test	
Identity (specific rotation)	passes test	
Identity (TLC)	passes test	
Appearance	white to almost white or colorless, irregular crystals	
Appearance of solution (50 g/l; water)	clear and not more intense in color than reference solution BY <sub>6</sub>	
Appearance of solution (100 g/l, water)	clear and colorless	
Transmittance of solution (100 g/l, water)	≥ 98.0	%
pH (100 g/l, CO <sub>2</sub> -free water)	4.7 - 6.2	
Spec. rotation (α 20/D, 80 g/l, hydrochloric acid 250 g/l, calc. on dried substance)	+21.0 to +23.5	°
Spec. rotation (α 20/D, 80 g/l, hydrochloric acid 6 mol/l, calc. on dried substance)	+21.5 to +23.5	°
Spec. rotation (α 20/D, 80 g/l, hydrochloric acid 6 mol/l, previously dried substance)	+21.5 to +23.5	°
Chloride (Cl) (argentometric)	16.5 - 17.1	%
Chloride (argentometric, calc. on dried substance)	16.5 - 17.1	%
Proteins	passes test	
Sulfate (SO <sub>4</sub> )	≤ 200	ppm
Phosphate (PO <sub>4</sub> <sup>3-</sup> )	≤ 200	ppm
Heavy metals (as Pb)	≤ 10	ppm
As (Arsenic)	≤ 1	ppm
Fe (Iron)	≤ 10	ppm
Other amino acids (TLC)	≤ 0.2	%
Related Compounds, total (TLC)	≤ 0.5	%
Related substances (TLC)	passes test	
Ninhydrin-positive substances (LC) (any ninhydrin-positive impurity)	≤ 0.2	%
Ninhydrin-positive substances (LC) (ammonium (570 nm))	≤ 0.02	%
Ninhydrin-positive substances (LC) (total impurities)	≤ 0.5	%
Residual solvents (ICH Q3C)	excluded by manufacturing process	

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Sulfated ash (600 °C)	≤ 0.1	%
Loss on drying (105 °C, 2 h)	≤ 0.20	%
Bacterial endotoxins	≤ 3.0	I.U./g
Bacterial endotoxins (ChP)	≤ 3.0	I.U./g
Microbiological test (total aerobic microbial count (TAMC))	≤ 10 <sup>2</sup>	CFU/g
Microbiological test (total yeast and mould count (TYMC))	≤ 10 <sup>1</sup>	CFU/g

Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental Impurities). Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (\*).

Compliance with pyrogens (according to ChP) is guaranteed by the test for bacterial endotoxins (ChP) and the production process.

Corresponds to Ph. Eur., BP, ChP, JP, USP.

Dr. Michael Memmel

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Responsible laboratory manager quality control

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