



# Specification

1.00286.0000 L-Glutamine EMPROVE® EXPERT DAB,JP,USP

## Specification

Assay (perchloric acid titration, calculated on dried substance)	99.0 - 101.0	%
Identity (IR-spectrum)	passes test	
Identity (specific rotation)	passes test	
Appearance	white to almost white, fine powder	
Appearance of solution (25 g/l; CO <sub>2</sub> -free water)	clear and colorless	
Spec. rotation ( $\alpha$ 20/D, 100 g/l, hydrochloric acid 2 mol/l, calc. on dried substance)	+31.5 to +33.0	°
Spec. rotation ( $\alpha$ 20/D, 40 g/l, water, calc. on dried substance)	+6.3 to +7.3	°
pH (25 g/l; CO <sub>2</sub> -free water)	4.0 - 6.0	
pH (20 g/l, CO <sub>2</sub> -free water)	4.5 - 6.0	
Chloride (Cl)	≤ 200	ppm
Sulfate (SO <sub>4</sub> )	≤ 200	ppm
Heavy metals (as Pb)	≤ 10	ppm
Cu (Copper)	≤ 25	ppm
Fe (Iron)	≤ 10	ppm
Mn (Manganese)	≤ 25	ppm
Ni (Nickel)	≤ 2	ppm
Zn (Zinc)	≤ 130	ppm
NH <sub>4</sub> (Ammonium)	≤ 0.1	%
Ninhydrin - positive substances (TLC)	≤ 0.5	%
Related substances (TLC)	passes test	
Residual solvents (ICH Q3C)	excluded by manufacturing process	
Sulfated ash (600 °C)	≤ 0.1	%
Loss on drying (105 °C; 3 h)	≤ 0.3	%
Bacterial endotoxins	≤ 2.0	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>2</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 (\*).

Corresponds to DAB, JP, USP

The original manufacturer name and address will be disclosed subsequent to signing a confidentiality agreement.

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Dr. Michael Memmel

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Responsible laboratory manager quality control

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