



Specification

1.12488.1000 N-Acetyl-DL-tryptophan EMPROVE® EXPERT Ph Eur, BP

Specification		
Assay (alkalimetric, calculated on dried substance)	99.0 - 101.0	%
Identity (IR-spectrum)	passes test	
Appearance	white to almost white, crystalline powder or colorless crystals	
Appearance of solution (10 g/l; sodium hydroxide solution 1 mol/l)	clear and not more intense in color than reference solution Y ₇ or GY ₇	
Opt. rotation (100 g/l, sodium hydroxide 1 mol/l)	-0.1 to +0.1	°
Fe (Iron)	≤ 10	ppm
NH ₄ (Ammonium)	≤ 200	ppm
Residual solvents (ICH Q3C)	excluded by manufacturing process	
Related substances (HPLC) (largest single impurity)	≤ 0.25	%
Related substances (HPLC) (Sum of all impurities)	≤ 0.5	%
Sulfated ash (600 °C)	≤ 0.1	%
Loss on Drying (105 °C)	≤ 0.5	%
Bacterial endotoxins	≤ 50	I.U./g
Total aerobic microbial count (TAMC)	≤ 10 ²	CFU/g
Total combined yeasts/moulds count (TYMC)	≤ 10 ¹	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 Ph. Eur., BP

Dr. Michael Memmel

Responsible laboratory manager quality control

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