



Specification

5.00299.0000 Nicotinamide EMPROVE® EXPERT Ph Eur,BP,JP,USP,FCC

Specification

Assay (perchloric acid titration, calculated on dried substance)	99.0 - 101.0	%
Assay (HPLC, calc. on dried substance)	98.5 - 101.0	%
Identity (IR-spectrum)	conforms	
Identity (wet chemistry)	conforms	
Identity (Melting point)	conforms	
Identity (UV/VIS)	conforms	
Appearance of solution (50 g/l; water)	clear (\leq 3 NTU) and colorless	
pH (50 g/l; water)	6.0 - 7.5	
Melting range (lower value)	\geq 128	°C
Melting range (upper value)	\leq 131	°C
Melting point	128 - 131	°C
Chloride (Cl)	\leq 210	ppm
Sulfate (SO ₄)	\leq 190	ppm
Pb (Lead)	\leq 2	ppm
Related substances (HPLC) (Major unspecified impurity)	\leq 0.10	%
Related substances (HPLC) (Sum of all impurities)	\leq 0.2	%
Residual solvents (ICH Q3C)	excluded by the production process	
Readily carbonisable substance	conforms	
Sulfated ash (600 °C)	\leq 0.1	%
Loss on drying (Vacuum; 18 h)	\leq 0.5	%
Total aerobic microbial count (TAMC)	\leq 10 ²	CFU/g
Total combined yeasts/moulds count (TYMC)	\leq 10 ¹	CFU/g
Bacterial endotoxins	\leq 10	I.U./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, JP, USP, FCC.

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

Dr. Sebastian Lips
Responsible laboratory manager quality control

This document has been produced electronically and is valid without a signature.