



Specification

5.00299.0000 Nicotinamide EMPROVE® ESSENTIAL Ph Eur,BP,USP,JP,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) (Ph Eur)	passes test	
Identity (IR-spectrum) (USP)	passes test	
Identity (coloring 1)	passes test	
Identity (coloring 2)	passes test	
Identity (UV/VIS-Spectrum)	passes test	
Appearance	White to almost white, crystalline powder	
Appearance of solution (50 g/l; water)	Clear, colourless, not more intense in color than reference solution BY ₇	
pH (50 g/l; water)	6.0 - 7.5	
Melting range (lower value)	≥ 128	°C
Melting range (upper value)	≤ 131	°C
Absorption ratio (A 245 nm/A 262 nm)	0.63 - 0.67	
Chloride (Cl)	≤ 210	ppm
Sulfate (SO ₄)	≤ 190	ppm
Pb (Lead)	≤ 2	ppm
Residual solvents (ICH Q3C)	excluded by production process	
Readily carbonisable substance	passes test	
Related substances (HPLC) (Major unspecified impurity)	≤ 0.10	%
Related substances (HPLC) (Sum of all impurities)	≤ 0.2	%
Sulfated ash (600 °C)	≤ 0.1	%
Loss on drying (Vacuum; 18 h)	≤ 0.5	%

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, USP, FCC, JP.

Dr. Sebastian Lips

Responsible laboratory manager quality control

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