



Specification

1.00162.0000 Boric acid powder, EMPROVE® ESSENTIAL Ph Eur,BP,JP,NF

Spec. Values		
Assay (alkalimetric, calculated on dried substance)	99.5 - 100.5	%
Assay (alkalimetric)	99.0 - 100.5	%
Identity	passes test	
Appearance of solution	passes test	
Completeness of solution	passes test	
Solubility in ethanol	passes test	
pH-value (3.3 %, water)	3.8 - 4.8	
Sulfate (SO ₄)	≤ 0.04	%
Heavy metals (as Pb)	≤ 0.0010	%
As (Arsenic) (*)	≤ 0.0003	%
Organic impurities	passes test	
Residual solvents (ICH Q3C)	excluded by manufacturing process	
Loss on drying (Silica gel)	≤ 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,JP,NF

Claudia Wiegand

Responsible laboratory manager quality control

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