



Specification

1.05867.0000 Magnesium oxide heavy EMPROVE® ESSENTIAL Ph Eur,BP,ChP,USP

Spec. Values		
Assay (complexometric, calc. on the ignited basis)	98.0 - 100.5	%
Assay (complexometric, calculated on the ignited basis according to USP)	96.0 - 100.5	%
Assay (complexometric, calculated on the ignited basis according to ChP)	96.5 - 101.0	%
Identity	passes test	
Appearance of solution (Ph Eur)	passes test	
Appearance of solution (ChP)	passes test	
Substances soluble in water (Ph Eur)	≤ 1.0	%
Substances soluble in water (USP)	≤ 1.0	%
Substances soluble in water (ChP)	≤ 2.0	%
Substances insoluble in acetic acid	≤ 0.1	%
Substances insoluble in acid (USP)	≤ 0.1	%
Substances insoluble in acid (ChP)	≤ 0.10	%
Free alkali (as NaOH)	≤ 0.6	%
Alkalinity (ChP)	passes test	
Carbonate (CO ₃)	passes test	
Chloride (Cl)	≤ 0.1	%
Fluoride (F)	≤ 0.08	%
Heavy metals (as Pb)	≤ 0.0020	%
Sulfate (SO ₄)	≤ 0.3	%
Al (Aluminium)	≤ 0.01	%
As (Arsenic)	≤ 0.0003	%
Ca (Calcium)	≤ 0.80	%
CaO (Calcium oxide)	≤ 1.5	%
Fe (Iron)	≤ 0.05	%
Mn (Manganese)	≤ 0.003	%
Ni (Nickel) (*)	≤ 0.0025	%
V (Vanadium) (*)	≤ 0.0025	%
Residual solvents (ICH Q3C)	excluded by manufacturing process	
Loss on ignition (900 °C)	≤ 8.0	%
Bulk density	≥ 0.25	g/ml

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, ChP, USP

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Kristin Starke

Responsible laboratory manager quality control

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