



Certificate of Analysis

1.05867.1000 Magnesium oxide heavy EMPROVE® ESSENTIAL Ph Eur, BP, USP
Batch K53255767

	Spec. Values		Batch Values	
Assay (complexometric, calc. on the ignited basis)	98.0 - 100.5	%	99.5	%
Assay (complexometric, calculated on the ignited basis according to USP)	96.0 - 100.5	%	99.5	%
Identity	passes test		passes test	
Appearance of solution	passes test		passes test	
Substances soluble in water	≤ 1.0	%	< 0.2	%
Substances insoluble in acetic acid	≤ 0.1	%	< 0.1	%
Substances insoluble in acid	≤ 0.1	%	< 0.1	%
Free alkali (as NaOH)	≤ 0.6	%	≤ 0.6	%
Chloride (Cl)	≤ 0.1	%	≤ 0.1	%
Sulfate (SO ₄)	≤ 0.5	%	≤ 0.5	%
Heavy metals (as Pb)	≤ 0.0020	%	≤ 0.0020	%
Al (Aluminium)	≤ 0.01	%	≤ 0.01	%
As (Arsenic)	≤ 0.0003	%	≤ 0.0003	%
Ca (Calcium)	≤ 0.8	%	≤ 0.8	%
Cr (Chromium)	≤ 0.0025	%	≤ 0.0025	%
Fe (Iron)	≤ 0.05	%	≤ 0.05	%
Na (Sodium)	≤ 0.1	%	≤ 0.1	%
Ni (Nickel)*	≤ 0.0025	%	0.0002	%
Si (Silicon)	≤ 0.05	%	≤ 0.05	%
V (Vanadium)*	≤ 0.0025	%	< 0.0001	%
Residual solvents (ICH Q3C)	excluded by manufacturing process		excluded by manufacturing process	
Loss on ignition (900 °C)	≤ 8.0	%	< 0.5	%
Bulk density	≥ 0.25	g/ml	≥ 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, USP

Date of manufacture (DD.MM.YYYY) 15.12.2020

Date of examination (DD.MM.YYYY) 28.04.2021

Minimum shelf life (DD.MM.YYYY) 31.12.2023

Claudia Wiegand

Responsible laboratory manager quality control

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