



# Specification

1.08846.0000 Zinc oxide EMPROVE® ESSENTIAL Ph Eur,BP,ChP,JP,USP

Specification		
Assay (complexometric, ZnO calculated on ignited substance)	99.0 - 100.5	%
Assay (USP)	98.0 - 102.0	%
Identity	passes test	
Carbonate and color of solution	passes test	
Free Alkali	passes test	
Chloride (Cl)	≤ 0.005	%
Sulfate (SO <sub>4</sub> )	≤ 0.005	%
As (Arsenic)	≤ 0.0002	%
Cd (Cadmium)*	≤ 0.0005	%
Fe (Iron)	≤ 0.0010	%
Pb (Lead)*	≤ 0.0010	%
Tl (Thallium)*	≤ 0.0005	%
Iron and other heavy metals	passes test	
Residual solvents (ICH Q3C)	excluded by manufacturing process	
Loss on ignition (850 °C)	≤ 1.0	%

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 (\*).

conforms to Ph Eur, BP, ChP, JP , USP

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

Dr. Dimitrij Ryvlin

Responsible laboratory manager quality control

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