METAPHARMACEUTICAL

N DE LOTE:
0230224

26/02/2024.

Certificate of Analysis

1.00662.5000 Sorbic acid EMPROVE® ESSENTIAL Ph Eur,BP,ChP,NF,FCC,E 200
Batch K55529062

	Spec. Values		Batch Values	
Assay (acidimetric, calc. on anhydrous substance)	99.0 - 101.0	%	99.5	%
Assay (HPLC, calc. on anhydrous substance)	98.0 - 102.0	%	99.6	%
Identity (IR)	passes test		passes test	
Identity (wet chemistry)	passes test		passes test	
Identity (Melting point)	passes test		passes test	
Identity (Melting range)	passes test		passes test	
Identity (UV/VIS-Spectroscopy)	passes test		passes test	
Identity (UV/VIS-Spectroscopy) (ChP)	passes test		passes test	
Appearance of solution (5 %; ethanol 96 %)	passes test		passes test	
Clarity and color of solution (ChP)	passes test		passes test	
Melting point	132 - 136	°C	135	°C
Melting range (lower value)	≥ 133	°C	133	°C
Melting range (upper value)	≤ 135	°C	135	°C
Heavy metals (as Pb)	≤ 0.001	%	≤ 0.001	%
As (Arsenic)	≤ 0.0003	%	≤ 0.0003	%
Cd (Cadmium)	≤ 0.001	%	≤ 0.001	%
Cu (Copper)	≤ 0.001	%	≤ 0.001	%
Hg (Mercury)	≤ 0.0001	%	≤ 0.0001	%
Pb (Lead)	≤ 0.0002	%	≤ 0.0002	%
Zn (Zinc)	≤ 0.001	%	≤ 0.001	%
Aldehydes (as Acetaldehyd)	≤ 0.15	%	≤ 0.15	%
Acetone	≤ 5000	ppm	≤ 5000	ppm
Other residual solvents (ICH Q3C)	excluded by the manufacturing process		excluded by the manufacturing process	
Thermal stability (105 °C)	No coloration		No coloration	
Water	≤ 0.5	%	0.1	%
Sulfated ash	≤ 0.1	%	< 0.1	%

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 the purity criteria on food additives according to the current European Commission Regulation.
Corresponds to Ph Eur, BP, ChP, NF, FCC, E 200

Date of manufacture (DD.MM.YYYY) 04.08.2023
Date of examination (DD.MM.YYYY) 09.10.2023
Minimum shelf life (DD.MM.YYYY) 31.08.2026

Julian Hofmann
Responsible laboratory manager quality control

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