



Certificate of Analysis

1.41354.1000 Polyvinyl alcohol 5-88 EMPROVE® ESSENTIAL Ph Eur,USP,JPE
Batch K55858054

	Spec. Values		Batch Values	
Identity (IR spectrum)	passes test		passes test	
Identity (Viscosity)	passes test		passes test	
Identity (Reaction with iodine)	passes test		passes test	
Identity (Reaction with iodine and boric acid)	passes test		passes test	
Identity (Reaction with ethanol)	passes test		passes test	
Appearance of solution (40 g/l, water)	passes test		passes test	
Appearance of solution (50 g/l, water)	passes test		passes test	
Water-insoluble matter (40 g/l, water)	≤ 0.1	%	< 0.1	%
pH-Value (40 g/l; water)	5.0 - 6.5		5.5	
Viscosity (40 g/l; water)	4.3 - 5.7	mPa•s	5.4	mPa•s
As (Arsenic)	≤ 2	ppm	< 2	ppm
Heavy metals (as Pb)	≤ 10	ppm	< 10	ppm
Crotonaldehyde (GC)	≤ 10	ppm	< 5	ppm
Acetic acid (alkalimetric)	≤ 0.5	%	0.1	%
Methanol (GC)	≤ 1.0	%	0.8	%
Methanol (GC) (JPE) ¹	≤ 1.0	%	≤ 1.0	%
Methyl acetate (GC)	≤ 1.0	%	< 0.1	%
Other residual solvents (ICH Q3C)	excluded by production process		excluded by production process	
Ester value	130 - 150		146	
Degree of hydrolysis (USP)	85 - 89	%	87	%
Degree of hydrolysis (JPE)	78 - 96	%	89	%
Acid value	≤ 3.0		0.8	
Saponification value	132 - 152		146	
Sulfated ash	≤ 1.0	%	0.4	%
Loss on Drying (105 °C)	≤ 5.0	%	1.5	%
Microbiological purity (Total aerobic microbial count (TAMC))	≤ 100	CFU/g	≤ 100	CFU/g
Microbiological purity (Total yeast and mould count (TYMC))	≤ 100	CFU/g	≤ 100	CFU/g
Bile-tolerant gram-negative bacteria (absent in 1 g)	conforms		conforms	
Escherichia coli (absent in 1 g)	conforms		conforms	
Pseudomonas aeruginosa (absent in 1 g)	conforms		conforms	
Staphylococcus aureus (absent in 1 g)	conforms		conforms	
Candida albicans (absent in 1 g)	conforms		conforms	
Salmonella (absent in 10 g)	conforms		conforms	

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 (*).

¹ Value measured in qualified external laboratory

Corresponds to Ph Eur,USP,JPE

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Date of manufacture (DD.MM.YYYY) 01.11.2023
Date of examination (DD.MM.YYYY) 28.03.2024
Minimum shelf life (DD.MM.YYYY) 30.11.2027

Dr. Sebastian Lips

Responsible laboratory manager quality control

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