Specification

1.41356.0000 Polyvinyl alcohol 28-99 EMPROVE® ESSENTIAL Ph Eur,JPE

	Specification	
Identity (IR spectrum)	passes test	
Identity (Viscosity)	passes test	
Identity (Reaction with iodine)	passes test	
Identity (Reaction with iodine and boric acid)	passes test	
Identity (Reaction with ethanol)	passes test	
Appearance of solution (40 g/l, water)	passes test	
Appearance of solution (50 g/l, water)	passes test	
Water-insoluble matter (40 g/l, water)	≤ 0.1	%
pH-Value (40 g/l; water)	5.0 - 6.5	
Dynamic viscosity (40 g/l; water)	23.8 - 32.2	mPa•s
Kinematic viscosity (40 g/l; water)	23.8 - 32.2	mm²/s
As (Arsenic)	≤ 2	ppm
Heavy metals (as Pb)	≤ 10	ppm
Crotonaldehyde (GC)	≤ 10	ppm
Acetic acid (alkalimetric)	≤ 0.5	%
Methanol (GC)	≤ 1.0	%
Methanol (GC) (JPE)[1]	≤ 1.0	%
Methyl acetate (GC)	≤ 1.0	%
Other residual solvents (ICH Q3C)	excluded by production process	
Ester value	9 - 11	
Degree of hydrolysis (JPE)	≥ 97	%
Acid value	≤ 3.0	
Saponification value	≤ 30	
Sulfated ash	≤ 1.0	%
Loss on Drying (105 °C)	≤ 5.0	%
Microbiological purity (Total aerobic microbial count (TAMC))	≤ 100	CFU/g
Microbiological purity (Total yeast and mould count (TYMC))	≤ 100	CFU/g
Bile-tolerant gram-negative bacteria (absent in 1 g)	conforms	
Escherichia coli (absent in 1 g)	conforms	
Pseudomonas aeruginosa (absent in 1 g)	conforms	
Staphylococcus aureus (absent in 1 g)	conforms	
Candida albicans (absent in 1 g)	conforms	
Salmonella (absent in 10 g)	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, JPE

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Responsible laboratory manager quality control

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