Certificate of Analysis

1.06008.0000 Methanol EMPROVE® ESSENTIAL Ph Eur,BP,JPE,NF
Batch I1421408

	Spec. Values		Batch Values	
Assay (GC)	≥ 99.5	%	99.9	%
Identity (IR)	conforms		conforms	
Identity B (NF)	conforms		conforms	
Identity (JPE)	conforms		conforms	
Appearance	conforms		conforms	
Clarity of solution	conforms		conforms	
Acidity or alkalinity	conforms		conforms	
Acidity	conforms		conforms	
Alkalinity (as NH_3)	≤ 3	ppm	≤ 3	ppm
Refractive index (n 20/D)	1.328 - 1.330		1.329	
Density (d 20 °C/20 °C)	0.791 - 0.793		0.793	
Boiling range (64-65°C)	≥ 95	% (v/v)	98	% (v/v)
Absorbance (at 230 nm)	≤ 0.15		0.089	
Absorbance (at 250 nm)	≤ 0.05		0.013	
Absorbance (at 270 nm)	≤ 0.02		0.001	
Absorbance (at 290 nm)	≤ 0.01		< 0.001	
The absorption curve is smooth	conforms		passes test	
Benzene (impurity A) (GC)	≤ 2	ppm	< 1	ppm
Acetone (GC)	≤ 0.001	%	< 0.001	%
Ethanol (GC)	≤ 0.005	%	< 0.005	%
Ethanol (JPE)	conforms		conforms	
Related substances (GC)	conforms		conforms	
Residual solvents class 3 (ICH Q3C)	< 0.5	%	< 0.5	%
Other residual solvents (ICH Q3C)	excluded by manufacturing process		excluded by manufacturing process	
Al (Aluminium)*	≤ 0.05	ppm	≤ 0.05	ppm
Cu (Copper)*	≤ 0.05	ppm	≤ 0.05	ppm
Zn (Zinc)*	≤ 0.05	ppm	≤ 0.05	ppm
Heavy metals	conforms		conforms	
Aldehydes and Acetone (as acetone)	≤ 0.003	%	< 0.003	%
Aldehyde and other foreign reducing substances	conforms		conforms	
Reducing substances	conforms		conforms	
Readily oxidizable substances	conforms		conforms	
Readily carbonizable substances	conforms		conforms	
Readily carbonizable substances (JPE)	conforms		conforms	
Evaporation residue	≤ 0.0010	%	< 0.0001	%
Water	≤ 0.10	%	< 0.01	%

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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, JPE, NF

Date of manufacture (DD.MM.YYYY) 09.04.2025
Date of examination (DD.MM.YYYY) 21.05.2025
Minimum shelf life (DD.MM.YYYY) 30.04.2030

Jeannette David
Responsible laboratory manager quality control

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