



# Specification

1.00971.2500 Ethanol 96% EMPROVE® EXPERT Ph Eur,BP,ChP

Specification		
Assay (m/m)	92.6 - 95.2	%
Assay (V/V)	95.1 - 96.9	%
Identity (IR)	conforms	
Identity 1 (ChP)	conforms	
Appearance	conforms	
Clarity and color of solution (ChP)	conforms	
Acidity or alkalinity	≤ 30	ppm
Acidity or alkalinity (ChP)	conforms	
Density (d 20 °C/20 °C)	0.805 - 0.812	
Density (d 20 °C/20 °C) (ChP)	≤ 0.8129	
Absorbance (at 240 nm)	≤ 0.40	
Absorbance (between 250 nm and 260 nm)	≤ 0.30	
Absorbance (between 270 nm and 340 nm)	≤ 0.10	
The spectrum shows a steadily descending curve with no observable peaks or shoulders	conforms	
Absorbance (ChP) (at 240 nm)	≤ 0.08	
Absorbance (ChP) (between 250 nm and 260 nm)	≤ 0.06	
Absorbance (ChP) (between 270 nm and 340 nm)	≤ 0.02	
Volatile impurities (GC) (Acetaldehyde and Acetal)	≤ 10	ppm
Volatile impurities (GC) (Benzene)	≤ 2	ppm
Volatile impurities (GC) (Methanol)	≤ 100	ppm
Volatile impurities (GC) (Total of other impurities)	≤ 300	ppm
Other residual solvents (ICH Q3C)	excluded by production process	
Evaporation residue	≤ 25	mg/l
Non-volatile matter	≤ 25	mg/l
Bacterial endotoxins	≤ 2.5	I.U./ml
Parameter with periodic testing		

Total aerobic microbial count (TAMC)	≤ 100	CFU/ml
Total combined yeasts/moulds count (TYMC)	≤ 10	CFU/ml

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.

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Jeannette David

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Responsible laboratory manager quality control

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