



Certificate of Analysis

Productname: ISOPROPYLALCOHOL

Inspection No: N00674/0226/536

Batchnumber: 25K14-T01-126166

Expiration date: 30.10.2027

Analysed according to: Ph.Eur.11.0

Customer: FAGRON a.s.

Sample Unit: 1 x 1500 ml

Batch Size: 171 x 1 l

Batch no. of vendor: 0701588B

	Requirement	Result	Unit	Standard remark
CHARACTERS				
Solubility	Conform	Conform		
IDENTIFICATION				
Identification B	1,376 - 1,379	1,377		Refractive index
Identification C	Conform	Conform		IR-spectrum
TESTS				
Appearance of solution	Conform	Conform		
Acidity or alkalinity	<=0,6	0,4	ml	0,01 mol/l NaOH
Absorbance	Conform	Conform		
Absorbance at 230 nm	<=0,30	0,11		
Absorbance at 250 nm	<=0,10	0,03		
Absorbance at 270 nm	<=0,03	0,01		
Absorbance at 290 nm	<=0,02	0,01		
Absorbance at 310 nm	<=0,01	0,00		
Benzene and related substances	Conform	Conform		GC
Benzene	<=2	<2	ppm (V/V)	
Total impurities apart from 2-butanol	<=0,3	<0,3	%	
Peroxides	Conform	Conform		
Non-volatile matter	<=20	0,0	ppm	
Water (Karl Fischer)	<=0,5	0,01	%	
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform		
Residual solvents	ICH Q3C	Conform		
Elemental impurities	ICH Q3D	Conform		
Nitrosamines	Risk evaluation	Conform		

Quality: Excipient

Performed by: QC Fagron a.s. (CZ)

Responsible: Mgr. Kateřina Špičková, QC
Mgr. Dominik Grék, DiS, QA/ RP

Date: 09.02.2026

Conclusion: **APPROVED**

This document has been produced electronically from our quality system and is valid without signature.

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