



Certificate of Analysis

Productname: ISOPROPYLALCOHOL

Inspection No: M00031/0125/536
Batchnumber: 24K27-T09-116697
Expiration date: 22.11.2026
Analysed according to: ČL 2023, Ph. Eur. 11.0

Customer: FAGRON a.s.
Sample Unit: 1 x 1500 ml
Batch Size: 300 x 1 l

Batch no. of vendor: 0701533B

	Requirement	Result	Unit	Standard remark
CHARACTERS				
Appearance	Clear, colourless liquid.	Conform		
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	0,3	ml	0,01 mol/l NaOH
Absorbance	Conform	Conform		
Absorbance at 230 nm	<=0,30	0,092		
Absorbance at 250 nm	<=0,10	0,0048		
Absorbance at 270 nm	<=0,03	0,01		
Absorbance at 290 nm	<=0,02	0,009		
Absorbance at 310 nm	<=0,01	0,009		
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		
Metallic residues	ICH Q3D	Conform		
Nitrosamines	Risk evaluation	Conform		

Quality: Excipient

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

Responsible: Mgr. Zdeňka Šinclová, QC
Mgr. Barbora Agatha Halouzková, QA/ QP

Date: 14.01.2025

Conclusion: **APPROVED**

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

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