

Certificate of Analysis

Productname: ISOPROPYLALCOHOL

Inspection No: I02879/0421/536
Batchnumber: 21B22-T15-085677
Expiration date: 15.01.2024
Analysed according to: ČL 2017-Dopl.2020,Ph.Eur.10.0
Original Manuf. Date: 15.1.2021

Sample Unit: 1 x 10 ml
Batch Size: 1 832 x 5 l

Identification of producer: V01258
Batch no. of vendor: 21501876

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, colourless liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification B	1,376 - 1,379	1,378		Refractive index	Fagron CZ
Identification C	Conform	Conform		IR-spectrum	Fagron CZ
TESTS					
Appearance of solution	Conform	Conform			Fagron CZ
Acidity or alkalinity	<=0,6	0,2	ml	0,01 mol/l NaOH	Fagron CZ
Absorbance	Conform	Conform		Proteins, light-absorbing impurities.	Fagron CZ
Absorbance at 230 nm	<=0,30	0,096			Fagron CZ
Absorbance at 250 nm	<=0,10	0,015			Fagron CZ
Absorbance at 270 nm	<=0,03	0,004			Fagron CZ
Absorbance at 290 nm	<=0,02	0,002			Fagron CZ
Absorbance at 310 nm	<=0,01	0,001			Fagron CZ
Benzene and related substances	Conform	Conform		GC	Contract Lab
Benzene	<=2	<2	µl/l		Contract Lab
Total impurities apart from 2-butanol	<=0,3	<0,3	%		Contract Lab
Peroxides	Conform	Conform			Fagron CZ
Non-volatile matter	<=20	0,0	µg/g		Fagron CZ
Water	<=0,5	0,3	%		Fagron CZ
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer

Name Fagron a.s. (CZ)
 Kontrolní laboratoř č. 536

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Performed by: Lucie Kubáňová DiS.

Responsible: Ing. Mgr. Kateřina Jokešová, QC
PharmDr. Ivana Urbánková, QA

Date: 04.05.2021

Conclusion: **APPROVED**

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