



Certificate of Analysis

Productname: ISOPROPYLALCOHOL

Inspection No: K05446/0923/536

Sample Unit: 1 x 10 ml

Batchnumber: 23D14-T02-105483

Batch Size: 1,464 x 1 l

Expiration date: 05.04.2025

Analysed according to: ČL2017-Dopl.2020, Ph.Eur.11.0

Original Manuf. Date: 4.1.2023

Identification of producer: V01858

Batch no. of vendor: 0701420B

	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	0,4	ml	0,01 mol/l NaOH	Fagron CZ
Absorbance	Conform	Conform		Proteins, light-absorbing impurities.	Fagron CZ
Absorbance at 230 nm	<=0,30	0,11			Fagron CZ
Absorbance at 250 nm	<=0,10	0,032			Fagron CZ
Absorbance at 270 nm	<=0,03	0,004			Fagron CZ
Absorbance at 290 nm	<=0,02	0,001			Fagron CZ
Absorbance at 310 nm	<=0,01	0,0008			Fagron CZ
Benzene and related substances	Conform	Conform		GC	Contract Lab
Benzene	<=2	<2	ppm		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	ppm		Fagron CZ
Water (Karl Fischer)	<=0,5	0,01	%		Fagron CZ
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	ICH Q3C	Conform			Data Producer
Metallic residues	ICH Q3D	Conform			Data Producer

Quality: Excipient

Performed by: Bc. Andrea Šmídová

Responsible: Mgr. Zdeňka Šinclová, QC
MVDr. Zdenka Borská, QP

Date: 07.09.2023

Conclusion: **APPROVED**

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