



Certificate of Analysis

Productname: Isopropylis myristas
Inspection No: I08817/1221/536
Batchnumber: 21I27-T01-091242
Expiration date: 30.11.2025
Analysed according to: ČL 2017-Dopl.2020, Ph.Eur.10.0
Original Manuf. Date: 7.11.2020

Sample Unit: 1 x 10 ml
Batch Size: 270 x 100 ml

Identification of producer: V00499
Batch no. of vendor: K53373666

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, colourless, oily liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
Relative density	About 0,853	0,854			Fagron CZ
IDENTIFICATION					
Identification B	Conform	Conform		GC	Contract Lab
TESTS					
Appearance of solution	Clear, <=Y7	Conform		10% m/V in methanol	Fagron CZ
Refractive Index	1,434 - 1,437	1,435			Fagron CZ
Viscosity	5 - 8	5	mPa.s		Fagron CZ
Acid value	<=1,0	0,12			Fagron CZ
Iodine value	<=1,0	0,13			Fagron CZ
Saponification value	202 - 212	206			Fagron CZ
Water	<=0,1	0,03	%		Fagron CZ
Total ash	<=0,1	0	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	<10	CFU/g		Contract Lab
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform			Data Producer
Residual solvents	CPMP/ICH/82 260/2006	Conform			Data Producer
Metallc residues	ICH Q3D on elemental Impurities	Conform			Data Producer
ASSAY					
Isopropyl tetradecanoate	>=80,0	103,3	%	GC	Contract Lab

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Performed by: Lucie Kubáňová DIS.
Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA
Date: 08.12.2021
Conclusion: APPROVED

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