



Certificate of Analysis

Productname: Isopropylis myristas

Inspection No: J09269/1222/536

Batchnumber: 22H29-T14-099542

Expiration date: 30.06.2024

Analysed according to: ČL 2017-Dopl.2020, Ph.Eur.10.0

Original Manuf. Date: 30.6.2022

Sample Unit: 1 x 10 ml

Batch Size: 199 x 100 ml

Identification of producer: V01666

Batch no. of vendor: PBS048175

	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	1,434			Fagron CZ
Viscosity	5 - 6	5	mPa.s		Fagron CZ
Acid value	<=1,0	0,063			Fagron CZ
Iodine value	<=1,0	0,25			Fagron CZ
Saponification value	202 - 212	208			Fagron CZ
Water	<=0,1	0,018	%		Fagron CZ
Total ash	<=0,1	0,0	%		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
Metallic residues	ICH Q3D on elemental impurities	Conform			Data Producer
ASSAY					
Isopropyl tetradecanoate	>=90,0	99,8	%	GC	Contract Lab

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

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Performed by: Ludmila Stochlebová

Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QP

Date: 11.11.2022

Conclusion: **APPROVED**

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