



## Certificate of Analysis

**Productname:** Decylis oleas

**Inspection No:** J10245/1222/536  
**Batchnumber:** 22J26-T04-099539  
**Expiration date:** 02.09.2024  
**Analysed according to:** ČL 2017, Ph.Eur.10.0  
**Original Manuf. Date:** 3.9.2022

**Sample Unit:** 1 x 50 ml  
**Batch Size:** 448 x 250 ml

**Identification of producer:** V00709  
**Batch no. of vendor:** 0026439310

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, pale yellow or colourless liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	0,860 - 0,870	0,865		Relative density	Fagron CZ
Identification B	130 - 140	137		Saponification value	Fagron CZ
Identification C	>=60,0	75,5	%	Oleic acid	Contract Lab
TESTS					
Relative density	0,860 - 0,870	0,865			Fagron CZ
Acid value	<=1,0	0,20			Fagron CZ
Iodine value	55 - 70	62			Fagron CZ
Peroxide value	<=10,0	2,92			Fagron CZ
Saponification value	130 - 140	137			Fagron CZ
Content of oleic acid	>=60,0	75,5	%	GC	Contract Lab
Water (Karl Fischer)	<=1,0	0,025	%		Fagron CZ
Total ash	<=0,1	0,0	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 <sup>3</sup>	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	<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

Quality: Excipient

<b>Name</b>	Fagron a.s. (CZ)	<b>Address</b>	Holická 1098/31m, Olomouc	<b>Phone No.</b>	+420585222590
	Kontrolní laboratoř č. 536	<b>Post Code</b>	779 00	<b>Fax No.</b>	+420 585 226 521

**Performed by:** Ludmila Stochlebová

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

**Date:** 30.11.2022

**Conclusion:** **APPROVED**

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