

Certificate of Analysis

Productname: **Arachidis oleum raffinatum**

Inspection No: I04978/0621/536

Batchnumber: **21E19-T12-085809**

Expiration date: 30.11.2022

Analysed according to: ČL 2017-Dopl.2019, Ph.Eur.10.0

Original Manuf. Date: 31.5.2021

Sample Unit: 0 x

Batch Size: 120 x 250 ml

Identification of producer: V00225

Batch no. of vendor: 157083

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Clear, yellowish, viscous liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
Relative density	About 0,915	0,914			Fagron CZ
Freezing point	About 2	2	°C		Fagron CZ
IDENTIFICATION					
Identification B	Conform	Conform		Composition of fatty acids	Contract Lab
TESTS					
Acid value	<=0,5	0,1			Fagron CZ
Peroxide value	<=5,0	0,36			Fagron CZ
Unsaponifiable matter	<=1,0	0,30	%		Fagron CZ
Alkaline impurities	Conform	Conform			Fagron CZ
Composition of fatty acids	Conform	Conform		GC	Contract Lab
Saturated fatty acids <C16	<=0,4	<0,1	%		Contract Lab
Palmitic acid	5,0 - 14,0	9,2	%		Contract Lab
Stearic acid	1,3 - 6,5	2,6	%		Contract Lab
Oleic acid	35,0 - 76,0	69,4	%		Contract Lab
Linoleic acid	8,0 - 43,0	12,6	%		Contract Lab
Linolenic acid	<=0,6	<0,1	%		Contract Lab
Arachidic acid	0,5 - 3,0	1,0	%		Contract Lab
Eicosenoic acid	0,5 - 3,0	1,5	%		Contract Lab
Behenic acid	1,0 - 5,0	2,0	%		Contract Lab
Erucic acid	<=0,5	0,2	%		Contract Lab
Lignoceric acid	0,5 - 3,0	1,1	%		Contract Lab
Water	<=0,1	<0,1	%		Contract Lab
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	Conform	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	Conform	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

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

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Performed by:

Lucie Kubáňová DiS.

Responsible:

Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA

Date:

15.07.2021



Conclusion:

APPROVED

This document has been produced electronically from our quality system and is valid without signature.

Name

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